SASMA

SOUTH AFRICAN SPORTS MEDICINE ASSOCIATION

The Voice of South African Sports Medicine

The South African Sports Medicine Association is an internationally recognised, a-political, non-profit, multidisciplinary professional and scientific society dedicated to co-ordinating and integrating a high standard of medical, scientific and educational services in sport, exercise and health in South Africa



Targeting school children in marketing campaigns for sports supplements: Is it ethical?

In April 2016 it was brought to SASMA's attention through a media release published on Netwerk 24*, that a campaign had been launched by a supplement company marketing their products to school children. The campaign takes the form of a competition, in which schools sign up to become agents for selling the company's supplements. Points are awarded for selling specific supplements, as well as hosting of certain promotional events publicising the company's supplements. In terms of the release, it was envisaged that the more supplements that were sold the more points would be awarded, and the school selling the most supplements/or with the most points at the end of the competition period would win a concert worth R100 000.

The campaign has sparked much debate and raised many questions about the ethics of supplement sponsorship for school sport. In response to this campaign, SASMA has issued a position statement emphasising that **SASMA does not support the use of supplements in healthy children.** The full position statement is available on P3 of this newsletter.

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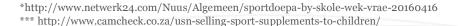
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As with any contentious issue, there are proponents and opponents in the debate. Opponents argue that children are "vulnerable consumers" and recognise that direct marketing creates expectations about a brand and also influences consumer behabiour in the short and long term. They argue that direct marketing of supplements in schools sends the message that supplements are needed in order to perform well in sport. Another of their concerns is the danger that children will become "hooked" on supplements from a young age exposing them to a number of risks - when use is not necessarily justified to start with.

Proponents will argue that if children have legal rights allowing them to exercise free will about medical/surgical procedures from as young as 12 years old, then they are not vulnerable and should also be allowed to exercise free will about their choice of "nutrition". Proponents may also emphasis the legal framework governing marketing and advertising to children, and argue that if campaigns are conducted according to these guidelines then they should be allowed. There is also the reality of the tough economic climate and the recognition that sponsorships have become increasingly lean and scarce. Organisations may feel pressure to take what they can get from whomever they get it, in order to be able to propel forward.

Despite being called to account**, at the time of publication of this newsletter, it seemed that the campaign was still going ahead. SASMA considers such aggressive marketing as highly irresponsible, dangerous and somewhat unethical as the youth who are involved in the schooling system are vulnerable targets in that they may choose to participate in sport and be under the impression that the relevant supplements have been approved and endorsed by WADA, SAIDS and SASCOC. Please be advised that neither WADA, SAIDS, SASCOC or SASMA have endorsed any supplement products.





SASMA 2020 Vision

2020 Vision:

- 1. Grow and diversify membership
- 2. Build a strong brand
- 3. Grow participation in the regions
- 4. Achieve multi-discipline integration

2016 Priorities

- 1. Rebranding
- 2. Website face-lift
- 3. Secure sponsors
- 4. Review accreditation policy and membership registration process for implentation in 2017



Last month collecting data -We need your input: SASMA Brand Equity Survey

Thank you to all the members who have already completed this survey.

For those of you who have not, we urge you to take 10minutes to help us help you! This survey will inform how we position ourselves as an organisation. Your feedback will influence who we approach as sponsors and who we choose to partner with as we journey forward. Please take the time to complete this 10 minute survey.

Complete the brand equity survey on https://www.surveymonkey.com/r/GZN6QHG



SASMA Position Statement on the use of supplements in school-going athletes



Released: May 2016

In keeping with international recommendations, it is the position of the South African Sports Medicine Association (SASMA) that healthy persons under the age of 18 years should not use sports supplements. Optimising dietary intake, quality of training, recovery strategies and sleep patterns have been clinically proven to have a far greater effect on overall health, athletic performance, and body composition than any dietary supplement tested to date.

What are sports supplements?

Sports supplements are a sub-category of dietary supplements that contain products claiming to enhance aspects of athletic performance, either directly or indirectly [1]. The South African Institute for Drug Free Sport (SAIDS) define sports supplements as "sources of nutrients and/or other substances, marketed and sold as such in the field of amateur and/or professional sport, with a nutritional or physiological effect whose purpose it is to supplement the normal diet, directly or indirectly alter/enhance body composition, enhance sporting performance, and/or assist with recovery following sporting activity" [2]. These products may include vitamins, minerals, amino acids, herbs, plants, metabolites or any concentration, extract or combination of these [1].

Of concern is the emerging evidence of dietary (including sport) supplements containing non-dietary ingredients such as steroids, stimulants and other potentially harmful ingredients that are often not specified as such on the product label [3].

A concerning lack of scientific evidence

There is a growing body of research being done globally investigating the efficacy, safety and ethics of the use of sports supplements, mainly in

adult populations. Contrary to product claims, only a small percentage of supplement ingredients have been shown to performance-enhancing potential (in adult athletes). The gains in performance are typically very small, not seen in all individuals and/or may even be detrimental performance in some. For the majority of supplements (and formulations) on the market, there is a lack of scientific backing for any claims of efficacy or safety, or claims are grossly overstated [4,5].

Due to the potential risk these products may pose in harming aspects of health, growth and development, these studies are typically not performed on healthy children and adolescents ^[5]. Therefore, the safety and efficacy of dietary supplement-use in healthy teenage athletes are largely unknown. Despite this, it is of major concern that cross-sectional studies conducted in high schools show an increasing trend of supplement-use in under 18 year old athletes ^[6]

A disturbing increase in adolescent supplement use

Despite this lack of efficacy shown in research, use of supplements in middle and high school is estimated to be 24 – 29% in the United States of America [6], while in South African studies,

55% of rugby-playing school boys (ages 13 and 16 – 17 years, N=222) reported using some form of supplement ^[7,8]. Research suggests that the use of performance enhancing supplements is higher in boys than girls, and starts as early as 10 years old, increasing in prevalence with age ^[5,9]. The decision to use a supplement and the choice of supplement used is often haphazardly made, and may be the result of pressure from poorly informed parents, coaches or peers ^[8,10].

The risks of supplement use

- The effects and side effects of supplement use in children have been poorly researched [5] and the interaction between different supplements and other medications that children may be taking (such as Ritalin and Roaccutane) are largely unknown.
- Apart from a lack of scientific evidence, there are a number of other risks associated with the use of sports supplements. Despite isolated improvements to manufacturing guidelines and quality control systems, the supplement industry remains largely unregulated and, therefore, products may be sold without the need to prove their safety and efficacy [9]; products could be mislabeled or contaminated, resulting in ill-health effects or inadvertent ingestion of a substance prohibited in sport that could result in a failed **doping** control test [11]. Cases of South African international athletes failing doping tests directly linked to the use of commercially available supplements have been well publicised [12].
- The emerging evidence of supplements containing pharmaceutical-grade ingredients (such as steroids, stimulants, pharmaceuticals) and other potentially

harmful ingredients such as 'fake' protein fillers e.g. melamine, are of great concern, especially for its potential detrimental impact on the growth and development of children and adolescents [13].

Evidence is mounting that even basic nutrients (e.g. vitamins, minerals, amino acids) can have harmful effects on health, training adaptations and performance when taken in doses that exceeds one's needs [1,5]. Unlike dietary sources of nutrients, supplements can more easily be ingested in unsafe dosages, especially when considering the 'more is better' and 'multiple supplement-use' mind-set that supplement manufacturers promote; and the issue of mislabeling ingredients and dosages so that you are not sure what and how much you are actually ingesting. For this reason one must carefully consider where you get your info on sports nutritional needs & supplement-use **from?** Sports supplement-use should only be considered under the appropriate guidance from suitably qualified and objective health professionals (e.g. registered dietitian), only once a need versus benefit and risk analysis have been done; once appropriate dietary intake has been optimised; and the exact dosage and duration of dietary supplement needs have been quantified [11,14].

Commercial exploitation of children is increasing

Of equal concern is the increasingly aggressive marketing and false claims of sports supplement manufacturers, which are likely to be driving the increase in supplement-use statistics. Marketing campaigns targeting school children include supplement companies sponsoring teams, being the naming sponsor for fields or stadia, and most recently and of great concern, campaigns that see schools

competing for points awarded for purchasing specific supplements and hosting promotional events, with the top scoring school winning a concert by a popular musician at the end of the year [15,16]. Research shows that adolescents are particularly vulnerable [17], spurring advertising and marketing debates about the ethics numerous supplement companies sponsoring youth sport specifically as there are health and dopingrelated concerns associated with this type of sponsorship [4].

Players, parents, coaches, schools and the broader public should all be concerned

These statistics and trends should be a cause for concern for all South Africans involved or interested in Sport.

According to the South African Institute for Drug Free Sport (SAIDS), the following supplements are reported to be commonly used by youth athletes [11]:

- 1. Vitamins/minerals
- 2. Protein Shakes and "Mass builders'
- 3. Creatine
- 4. Pro-hormones
- 5. Stimulants
- 6. Sport and caffeine-containing energy drinks
- 7. Herbal preparations

A detailed review of the evidence for and against the use of these products is provided in the SAIDS Position Statement on the use of supplements in sport in school-going youth [11]. Of particular concern is that research repeatedly suggests that youth athletes have a poor understanding of the principles of sports nutrition and, in most_cases, the use_of

supplements is unwarranted [7].

A gateway to doping

Furthermore, some research supports that the use of sports supplements in school based sport represents a "gateway" to the use of anabolic steroids and other prohibited substances, and predicts a significantly higher risk for substance abuse including alcohol [18,19]. The use of banned substances (doping) in elite sport is a well-established problem, and there exists evidence that the seeds of such behaviour are planted at junior sports level [5].

SASMA discourages the use of sports supplements by children

SASMA's position is that, as a general rule, supplements are not required and should be avoided in adolescent and youth athletes. Youth athletes should be encouraged to optimise their diet, refine training habits, and improve recovery strategies in order to boost health and athletic performance.



SASMA endorses the 2011 guidelines published by SAIDS [11], which include:

• Supplement and nutrition education are important. Adolescents need to be taught about the myths and facts behind supplement use based on sound health and nutrition principles and credible knowledge. This teaching should be done by health professionals with appropriate credentials, objectivity, ethical standards and up-to-date knowledge on the topic.

References

- Children and adolescents should stay clear of supplement use as far as possible. Only where a specific dietary gap has been identified by a suitably qualified health professional may supplementation* be used in conjunction with dietary optimization, *such as vitamin and mineral supplementation, carbohydrate sports -drinks, -gels, -bars, concentrated sources of carbohydrates, for those doing prolonged vigorous sports activities, and chosen according to "low risk" criteria. This should ideally be done with the guidance of a registered dietician.
- Carbohydrate supplements (drinks, gels, energy bars) are generally low risk, but care should be taken when combined with other substances. Choose reliable brands and evaluate manufacturer track record/history. These products are generally only warranted for those who train hard/frequently/ for long hours/at high intensities.
- Products like creatine and caffeine are not banned substances, however, they have not been proven to be safe and effective in healthy children and adolescents. Note that there is a risk of contamination even in these substances.
- Be extremely cautious of supplements advertising 'muscle building' and 'fat burner' or 'enhanced energy' effects, or supplements containing herbal ingredients as these are likely to contain banned substances such as anabolic steroids, pro-hormones, or stimulants.
- Guard against individuals closely involved with youth athletes (trainers, coaches, teachers, and even some health professionals etc.) that become distributors and sell 'performanceenhancing' supplements to children and adolescents. This is considered a serious conflict of interest.

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SASMA Notice Board Highlighted this month

4th International Scientific Tendinopathy Symposium, 22 – 24 October, Cape Town

The 4th International Scientific Tendinopathy Symposium (ISTS) will be hosted by the University of Cape Town (UCT) at the Sports Science Institute of South Africa (SSIAS) in Cape Town from the 22nd – 24th October 2016. The invited speakers and delegates of this biennial conference represent the pre-eminent international authorities in basic and clinical tendon research.

Abstract Submission Deadline: 31 May 2016 For more info visit: www.ists2016.uct.ac.za



IOC Advanced Team Physician Course 17 - 19 Nov, Cape Town

Scientific programme and registration details are available on: http://www.ioc-preventionconference.org/atpc2016/

An experienced faculty are fully committed to ensure that this 3-day event will be at least as successful as the seven memorable previous IOC Advanced Team Physician Courses. This will be a team physician course geared towards the practical issues of working with high-level athletes in a team sports setting.

We will learn from the best! Delegates will receive cases illustrating specific scenarios, which we will address through small groups discussions, plenary lectures and panel discussions.

Our aim is to bring together 110 delegates with experience as team physicians to share new knowledge and challenge each other in open discussions.

We have also created a social program to foster discussions and create an excellent possibility for networking outside the scientific sessions. We know from previous experience that this opportunity is highly appreciated.

The IOC Advanced Team Physician Course is open to a limited number of experienced sports physical therapists.

IOC World Conference for Prevention of Injury and Illness in Sport 16-18 March 2017

Registration and scientific programme: http://www.ioc-preventionconference.org/

SASMA Members get a discount of 150€ on the registration fee!

The 2017 IOC World Conference will follow the model of the 2005 Congress in Oslo, the 2008 Congress in Tromsø and the 2011 & 2014 IOC World Conference in Monaco by presenting a multidisciplinary perspective on injury and illness prevention for different sports and different injury/illness types, including lectures on intervention methods, epidemiology, risk factors and injury mechanisms.

The three-day programme will include 5 keynote lectures, 33 symposia and numerous workshops, in addition to free communications and posters. Abstracts presented at the Conferences will be published in a special themed issue of the British Journal of Sports Medicine (BJSM). It is our intention to bring the world leaders in sport and sports medicine together in a joint effort to prevent injury and illness in sport!



2016 Conference Calendar

31 May - 4 Jun	ACSM, 63 rd Annual Meeting, Boston, Massachusetts
8 Jun - 11 Jun	International Society of Behavioural Nutrition and Physical Activity (ISBNPA), Cape Town, RSA
24 -26 Jun	HPC International Congress for Sports Performance, Pretoria, RSA
6 – 9 Jul	Eur College of Sports Science 21 st Annual Congress, Vienna, Austria.
29 Sep – 2 Oct	FIMS 34 th World Congress of Sports Medicine, Ljubljana, Slovenia
22 – 24 Oct	4 th International Scientific Tendinopathy Symposium, Cape Town, RSA
17 – 19 Nov	IOC Advanced Team Physician

Course, Cape Town,

RSA

VACANCIES

Physiotherapist





The School of Therapeutic Sciences at the University of the Witwatersrand has established a multidisciplinary state of the art, best-practice Sports Clinic, the sportsclinic@wits.

We require the services of a qualified physiotherapist, with an interest and experience in sports and exercise physiotherapy to work in the clinic as an accredited service provider. This will be in a group practice. This opportunity requires provision of service on a part time basis initially, with the possibility of expansion. The contract is negotiable. Start: June 2016 or earlier

All interested practitioners should submit their CV and proof of professional registration to Irene Janse van Noordwyk

(Irene.JanseVanNoordwyk@wits.ac.za) no later than 16 May 2016.

Dietician

FUTURELIFE®
Dietitian/Nutrition
Representative vacancy:
Eastern Cape



FUTURELIFE® are looking for a dynamic, innovative, passionate and self-motivated dietitian/nutritionist to join our exciting team as a Dietitian/Nutrition Representative to be based in the Eastern Cape.

Kay Requirements:

Appropriate Degree in Dietetics and/or Nutrition; Driver's license; Willing to be based in Eastern Cape (anywhere from East London up the East coast or inland thereof)

Commencement: Within July 2016

Closing date for applications: End of day 18 May 2016

If you think you meet the above criteria and would like to be part of this exciting opportunity, please submit a detailed C.V with certified copies of your educational certificates (degree, HPCSA number, etc) and a cover letter to: Email: lara@futurelife.co.za

South African Institute for Drug Free Sport

- Expert Panels

1. Doping Control Review Commission



Objectives/Key Activities:

To review, analyse and make scientifically based recommendations on the following:

- Adverse Analytical Findings (AAF)
- Athlete Biological Passport (ABP) Blood Profile
- Steroid Profiles Urine Profile
- Violation of Anti-Doping Rules by Athletes Recommendations from the expert panel determine the nature of the doping charge against an athlete.

Criteria for Expert Panel:

Applicants with advanced qualifications (MD, PhD etc.) in the following professional areas; sports medicine, exercise physiology, pharmacology, haematology, endocrinology. A minimum of 15 years professional experience in an area of specialization is recommended.

Time Commitment:

Approximately 20 hours a month. All reviews are done remotely via email.

Please forward CV and a cover letter to recruitment@drugfreesport.org.za (Ref: DCRC 2016)

For more information on SAIDS, please visit www.drugfreesport.org.za

Therapeutic Use Exemption Committee Member



Role: To review the granting or denial of Therapeutic Use Exemptions (TUEs) for athletes competing in South Africa at both National and International level competitions.

Members:

Medical doctors with an understanding of Anti-Doping regulation and experience in the care and treatment of athletes and a sound knowledge of clinical, sports and exercise medicine are preferred.

Objectives/Key Activities:

To review the granting or denying of TUEs for athletes competing in South African competitions at both the international and National levels, in accordance with the International Standard for TUEs.

Time Commitment:

Approximately 10 hours a month on average of 250 TUE applications are processed per annum. Processing would be conducted remotely and via emailed correspondence.

Please forward CV and a cover letter to recruitment@drugfreesport.org.za (Ref: TUEC_2016) For more information on SAIDS, please visit www.drugfreesport.org.za

Closing date: 30 days from date of publication at 16h00. No late or faxed nominations will be accepted. If you have not been contacted within two (2) months of the closing date of this advertisement, please accept that your application was unsuccessful.

Pssst....More for you to chew on!

SPORT SCIENCE COLLECTIVE Issue 2 May 2016.

A newsletter aimed at Sports Scientists, the SPORT SCIENCE COLLECTIVE has 3 aims:

- 1. Deliver practical, informative, and positive information
- 2. Connect sport science PEOPLE
- 3. Progress, promote, and protect sport science as a profession in South Africa

Access the free newsletter using the following link:

https://drive.google.com/open?id=oB7kUBueokBft aW5NMG92T3VNVWc

From the BJSM Blog

blogs.bmj.com/bjsm/

The Maria Sharapova drug story: What's the evidence? Does Meldonium treat heart conditions and diabetes?

17 Apr, 16 | by Karim Khan

By David Nunan @DNunan79



Many have commented on the <u>how</u>, <u>who</u>, <u>what</u> and <u>ethical</u> implications following <u>Maria Sharapova's</u> <u>shock revelation of her failed drugs test</u>. Few have looked in more depth at the why?

The evidence for "why?" in this case falls in to two key areas. First is the evidence that Mildronate (or Meldonium) is indicated for the conditions Maria was taking it for, apparently to "combat a magnesium deficiency, heart problems and because of a family history of diabetes".

Second, is the question of whether the drug enhances exercise and sporting performance. I will tackle the second issue in my next blog; here I focus on the question:

"What is the evidence for Mildronate/Meldonium to treat heart problems (abnormal ECG), indications for diabetes (familial history) and magnesium deficiency in a 17-year-old athlete?"

Meldonium's <u>Wikipedia page</u> provides background information on the drug, such as common trade names ("<u>Vazonat</u>", "Idrinol", "Msmall", "Quaterine", "MET-88", and "THP"), its chemical name (trimethylhydrasine), one of its <u>Latvian</u> <u>manufacturers</u>, Grindeks, and its widely adopted use throughout Latvia and other Baltic states. It isn't licensed in the United States or Europe.

A number of clinical trials are cited, unfortunately the links to each of these are dead but they all appear to be conference proceedings.

Grindeks' own website <u>highlights</u> pre-published results from a 2010

Russian/Latvian/Lithuanian/Ukrainian collaborative phase III RCT. Mildronate proved safe and effective for treatment of angina. The drug's creator wrote:

"As the author of this medication I have always been sure about the therapeutic effectiveness of Mildronate®..." and "[R]esults of the just-finished multinational clinical trial once more approve effectiveness and the high safety of Mildronate® in treatment of angina in combination with the standard therapy."

The <u>webpage</u> does not provide enough detail to ascertain if the study was published in a peer-reviewed journal nor if the protocol was pre-registered.

However, a bit of digging around the website reveals a <u>publication</u> for this study in *Seminars in Cardiovascular Medicine*.

A double-blind, placebo-controlled trial in 371 chronic CHD patients with stable angina aged between 24 and 82 yrs of age (mean ~61 yrs) was performed to assess the effect of 12 months treatment with mildronate on exercise capacity as primary outcome (so not angina onset). In the 278 that completed the study (no details given for drop outs), patients randomized to mildronate improved performance on a cycling ergometer test by an average of 55 seconds.

My comparison of the study against the CONSORT statement suggests several limitations. I couldn't find methods for (i) the sequence generation of the random numbers needed for randomisation, (ii) allocation concealment or (iii) blinding of investigators. Again, diverging from CONSORT, there is no statistical analysis section. Therefore, I respectfully posit that the findings from this paper would be classed as having risk of bias for internal validity. This would be considered a limitation were a group like the FDA (Federal Drug Agency) asked to approve the drug for clinical practice.

There appears no pre-registered protocol although reporting bias based on methods described in the paper appears low. Adverse effects were not considered as an outcome nor any reported. No information on funding is given and no conflicts of interest are stated. The study lead author and one of its principle investigators are <u>Editors for</u> the journal in which it was published.

But I've just committed one of the sins of a none-EBM approach – <u>cherry-picking</u> (2nddefinition in link). Perhaps you want a more systematic approach?

A search of PubMed for "Mildronate" OR "Meldonium" gives 217 returns, 108 of which are in Russian. Filtering for systematic reviews in humans – which would give the highest <u>level of evidence</u> for the efficacy and effectiveness as a treatment for these conditions – gives zero returns.

Filtering for the next level of evidence (RCTs) and only for Mildronate/Meldonium or its drug class gives 22 hits (Figure 1); 11 of which are RCTs (9 in Russian), 4 pharmacokinetic studies (all in English) and 7 studies (all in Russian) where study design/methods are unclear.

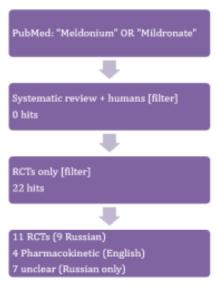


Figure 1. PubMed search results

Studies were published between 1989 and 2015. The study already looked at in detail on the manufacturer website was not picked up in the search.

First thing of note is that there are a number of RCTs assessing the efficacy of Mildronate/Meldonium but no systematic review.

Ascertaining details from each of the 11 RCTs is limited by language restrictions. It appears the largest included 512 patients and the smallest only 35. Clinical conditions assessed in each trial are listed below.

Patient populations included in 11 RCTs of
Mildronate/Meldonium

- Coronary heart disease (CHD) [2 studies]
- Post MI heart failure with [2 studies] or without [1 study] type 2 diabetes (T2DM)
- Ischaemic stroke [1 study]
- Post MI [1 study] and after PCI [1 study]
- CVD [2 studies]
- T2DM with neuropathy [1 study]

I note that I cannot read the Russian papers so my comments are restricted to English language papers. It may be that the Russian studies are high quality and cover off the limitations I see in the English language publications. Only one of the English language studies was <u>pre-registered</u>. However, this was done after the trial had started. (On a separate note, I have many reservations about current processes for trial registration — more on this issue here).

None of the English language studies assessed patients with ECG abnormalities specifically

(although these will be indicated in a number of the

patient groups), nor pre-diabetes or magnesium deficiency, nor in adolescents!

Focusing on English language evidence of the drug for treating ECG abnormalities, the abstract from one <u>study</u> reports a trial of 1000mg/day **intravenous** Mildronate for 10-14 days in 30 patients aged 45 to 75 years with CHD led to "a decrease in the number of arrhythmia episodes."

A second English language <u>trial</u> abstract (with only 2 authors) reported that 12 weeks Mildronate (no information on delivery or dose) "decreased the number of epinventricular extrasystoles (p = 0.002) and the number of paroxysmal rhythm disturbances (p = 0.001)" in 67 myocardial infarction survivors aged 40 to 70 years of age.

It's not possible to assess the risk of bias, the source of funding or conflicts of interest for these English language trials. Neither trial was preregistered. Taking a leap of faith, let's assume these trials are at low risk of bias/no conflict of interest etc., they suggest that short-term (intravenous) use of Mildronate <u>may</u> reduce the frequency of ECG abnormalities in people aged 40 to 75 years of age and suffering from CHD or having survived a myocardial infarction.

But these English language studies are too small to be conclusive. A lack of information on delivery mode in one trial impacts on external validity as it is <u>sold</u> to be taken either orally or intravenously.

So what about treating 'indicators for diabetes'?

The <u>trial</u> reports "a statistically significant improvement in renal functioning: GFR [glomerular filtration rate] increased by 20% vs 2% (p < 0.05); proportion of patients with exhausted FRR [function renal reserve] decreased (p < 0.05)" and "A hypoglycemizing ability of Mildronate was noted" in 30 patients aged 43 to 70 with heart failure and T2DM randomised to 1 g/day Mildronate (no information on delivery mode) for 16 weeks.

A second open label <u>trial</u> by the same group found "Mildronate administration improved clinical condition of the study group vs controls by neuropathy and symptoms count scales." in 70 patients with T2DM & neuropathy randomised to 1 g/day for 12 weeks.

Again, it's not possible to assess bias and potential conflicts of interest. External validity would appear poor given the patient population and no data on glycaemic control!

Evidence for Mildronate/Meldonium in magnesium deficiency is easy! However, cardiac arrhythmia may be a symptom of a <u>magnesium abnormality</u> (too much or too little) that provides a (albeit poor) mechanistic link for Mildronate/Meldonium use.

Overall, there is some English-language evidence from a few small RCTs that short-term use of Mildronate/Meldomium at 1g/day (intravenously but possibly orally) reduces occurrence of cardiac arrhythmia in high risk (older) patients with CHD. It may also improve renal function in heart failure

patients with T2DM and neuropathy symptoms in T2DM.

However, the English-language trials providing this "evidence" are very likely too small and there is high uncertainty about the risk of bias, the quality of the data, conflicts of interest and a lack of data on potential harms.

The question begs "Does the evidence support the decision of the family physician to prescribe Mildronate to a year 17 year old athlete for *treatment* of an abnormal ECG, indicators of diabetes and magnesium deficiency over a 10 year period?"

What would you say if you were on the jury?

In my followup blog (Next week!) I'll examine whether Mildronate/Meldonium appears to enhance performance.

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Be Inspired

"May the space between where I am and where I want to be inspire me."





Please contact us with comments or suggestions.

Best Wishes!

Phatho Zondi **SASMA President**

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