# Impact of glucosamine supplementation on gut health

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
04/06/2021		Protocol		
<b>Registration date</b> 08/06/2021	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
06/07/2021	Other			

#### Plain English summary of protocol

Background and study arms

Glucosamine (GLU) is a natural compound found in cartilage and supplementation with glucosamine has been shown to improve joint health and has been linked to reduced mortality rates. GLU is poorly absorbed and may exhibit functional properties in the gut. The purpose of this study was to examine the impact of glucosamine on gastrointestinal function as well as changes in fecal microbiota and metabolome (bacteria present in the gut and in feces).

Who can participate?

Healthy male and females subjects between the ages of 18 - 50 years

What does the study involve?

Participants were randomly allocated to receive supplementation with glucosamine or placebo daily for 21 days. After 3 weeks break, the participants then received the opposite allocation for a further 21 days. Collection of stool samples 4 times during the study.

What are the possible benefits and risks of participating? Improved gut health, no risks

Where is the study run from? Lindenwood University (USA)

When is the study starting and how long is it expected to run for? April 2018 to September 2019

Who is funding the study?
TSI Group Ltd., Missoula, MT, USA

Who is the main contact?
Dr Chad M. Kerksick, ckerksick@lindendwood.edu

## Contact information

#### Type(s)

Scientific

#### Contact name

**Prof Chad Kerksick** 

#### **ORCID ID**

https://orcid.org/0000-0003-0458-7294

#### Contact details

209 S Kingshighway St St Charles, MO United States of America 63301 +1 636.627.4629 ckerksick@lindenwood.edu

#### Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### **IRAS** number

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

INC-LINU-2018-12

# Study information

#### Scientific Title

Impact of glucosamine supplementation on gut health, microbiota and metabolome

#### Acronym

GluGutHealth

#### Study objectives

Glucosamine (GLU) is a natural compound found in cartilage and supplementation with glucosamine has been shown to improve joint heath and has been linked to reduced mortality rates. GLU is poorly absorbed and may exhibit functional properties in the gut. The purpose of this study was to examine the impact of glucosamine on gastrointestinal function as well as changes in fecal microbiota and metabolome.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 18/10/2018, Lindenwood University Institutional Review Board (IRB) (209 South Kingshighway, Library and Academic Resources Center Room 243, St. Charles, MO USA 63301; +1-636-949-4730; irb@lindenwood.edu), ref: # IRB-19-8,

#### Study design

Interventional double-blind randomized crossover trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Home

#### Study type(s)

Quality of life

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

#### Health condition(s) or problem(s) studied

Impact of glucosamine supplementation on gut health in healthy subjects

#### **Interventions**

On a daily basis, participants were instructed to ingest 3,000 mg of Glucosamine Hydrochloride (GlucosaGreen® TSI Group Ltd. MT, USA) or a matching placebo (maltodextrin), identical in appearance for a total of 21 days. Following a three week washout period participant ingested the other supplement for 21 days. Randomization was completed online (Random.org).

#### Intervention Type

Supplement

#### Primary outcome measure

- 1. Fecal metabolome (short-chain fatty acids, amino acids, amino acid breakdown products, nucleotide breakdown products, microbially produced fermentation products, likely diet-derived products) is measured using stool samples at baseline, after 3 weeks of supplementation, after 3 weeks of washout, after 3 weeks of supplementation
- 2. Fecal Microbiota is measured using stool samples at baseline, after 3 weeks of supplementation, after 3 weeks of washout, after 3 weeks of supplementation and analyzed for microbiota diversity, bacterial taxa)
- 3. Stool consistency will be analyzed via the Bristol Stool Chart at baseline, after 3 weeks of supplementation, after 3 weeks of washout, after 3 weeks of supplementation
- 4. Gut health will be measured via the Gastrointestinal Symptom Rating Scale (GSRS) questionnaire at baseline, after 3 weeks of supplementation, after 3 weeks of washout, after 3 weeks of supplementation

#### Secondary outcome measures

Safety measured using adverse event monitoring throughout the study

#### Overall study start date

01/04/2018

#### Completion date

01/09/2019

# **Eligibility**

#### Key inclusion criteria

- 1. Between the ages of 18 50 years
- 2. Body mass index between 18.5 27 kg/m<sup>2</sup>
- 3. Weight stable for the past three months (less than 5% variation in body mass)
- 4. Free from all cardiovascular, pulmonary, autoimmune, musculoskeletal, gastrointestinal, psychological, or other diseases or disorders, as reported in their medical history

#### Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

11

#### Total final enrolment

11

#### Key exclusion criteria

- 1. Diagnosed with or were being treated for celiac disease, lactose intolerance, digestive insufficiencies, or other gastrointestinal complications such as irritable bowel syndrome, ulcerative colitis, etc.
- 2. A current smoker or had guit within the past six months
- 3. Currently using anabolic steroids or any illicit or recreational drugs
- 4. Currently taking any antibiotics, probiotics or medication known to impact study outcomes
- 5. Actively trying to lose weight which included participating in diets that would impact study outcomes (ketogenic or low carbohydrate diet)

#### Date of first enrolment

19/10/2018

#### Date of final enrolment

01/12/2018

### Locations

#### Countries of recruitment

United States of America

# Study participating centre Lindenwood University

Exercise and Performance Nutrition Laboratory School of Health Sciences 209 S Kingshighway St St. Charles, MO United States of America 63301

# Sponsor information

#### Organisation

TSI Group

#### Sponsor details

135 W Main St Missoula, MT United States of America 59802 +1 (877) 549-9123 customersupport@us.tsigroupltd.com

#### Sponsor type

Industry

#### Website

https://tsigroupltd.com/

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

TSI Group

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in peer-reviewed scientific journal.

#### Intention to publish date

01/07/2021

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Dr Chad M. Kerksick, ckerksick@lindendwood.edu

#### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/06/2021	06/07/2021	Yes	No