

# Impact of glucosamine supplementation on gut health

<b>Submission date</b> 04/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/07/2021	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

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 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.

**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

## Study type(s)

Quality of life

## 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(s)

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

## Key secondary outcome(s)

Safety measured using adverse event monitoring throughout the study

## 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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 quit 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

## Funder(s)

### Funder type

Industry

### Funder Name

TSI Group

## Results and Publications

### 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?
<a href="#">Results article</a>		24/06/2021	06/07/2021	Yes	No