

Impact of glucosamine supplementation on gut health

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

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 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

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/m²
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 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

Sponsor details

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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