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Impact of glucosamine supplementation on gut health

Submission date	Recruitment status	[_] Prospectively registered
04/06/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/06/2021	Completed	[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

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 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,

Primary study design
Interventional

Study design
Interventional double-blind randomized crossover trial

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/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

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?
Results article		24/06/2021	06/07/2021	Yes	No