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The effects of 12-week whey protein supplementation on upper respiratory illness

Submission date
12/12/2023

Recruitment status
No longer recruiting

Registration date
13/12/2023

Overall study status
Ongoing

Last Edited
28/04/2025

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Upper respiratory tract infections (URTI) are the most common illness in a healthy population and athletes. Although the general consensus is that moderate amounts of exercise are beneficial to immunity, it has been shown that strenuous/prolonged exercise may increase the risk of contracting an infection. In fact, URTIs are second only to injuries for training days missed in preparation for sporting competitions. In addition, other lifestyle factors (i.e. increased exposure) also contribute to a higher than 'normal' reported incidence rate for URTIs in certain groups of athletes. With URTIs having both direct (if suffered during/near competition) and indirect (disruption of training due to missed sessions) risks to an athlete's performance, treatments to reduce the risk of contracting these infections, or reducing their severity or duration, are of interest to researchers. The present study aims to test whether a 12-week whey protein concentrate (WPC) supplementation decreases URTI incidence in active people.

Who can participate?
Healthy volunteers over the age of 18 years old who are free from injury, illness (no URTI within the last 4 weeks). Participants must be deemed 'healthy' via a pre-screening health questionnaire and have no allergies or intolerances to dairy or pea protein, or any other ingredients found in the study products. Participants must also engage in moderate to intense exercise regularly (3+ hours/week).

What does the study involve?
Those who agree to take part will need to complete a pre-screening health questionnaire to determine whether they're eligible to take part and will be required to provide their written informed consent. Participants will consume 40g/day of either a WPC or a placebo (containing pea protein) for 12 weeks. During this time, they will complete a daily self-report URTI symptom questionnaire. On days in which URTI symptoms do occur, participants will be asked to take a self-swab from their throat and nose using a swabbing device for later analysis (to screen for URTI-causing pathogens). Participants will visit the laboratory every four weeks (weeks 0, 4, 8 and 12) during the study to complete the Cohen-Hoberman Inventory of Physical Symptoms (CHIPS) and to provide blood and saliva samples, for later analysis of stress- and immune-related biomarkers and dairy lipid levels.

What are the possible benefits and risks of participating?
Benefits: Participants will receive a 12-week supply of high-quality protein. They will also be provided with reasonable expenses to ensure they are not left out of pocket by taking part.
Risks: The likelihood of adverse reactions or side effects to the use of the product is low in those who are not allergic to any of the ingredients. Blood samples taken via venepuncture may cause minor pain and distress for some participants, and there is a very small risk of infection. These risks are minimised as all procedures will be performed by phlebotomy-trained individuals and will follow strict protocols to ensure safety and hygiene. Taking the oral/nasal swab may cause mild discomfort (e.g. some people find a throat swab either tickly or a bit unpleasant) but this only lasts a few seconds. There are no significant long-term risks from this.

Where is the study run from?
University of Kent (UK)

When is the study starting and how long is it expected to run for?
August 2023 to September 2025

Who is funding the study?
Volac International Ltd. (UK)

Who is the main contact?
Will Searle, ws215@kent.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UoK SSES REAG Ref No. 40_20_23

Study information

Scientific Title
The effects of 12-week whey protein supplementation on immune function and upper respiratory illness in active people

Study objectives
Null: There will be no difference in self-report upper respiratory tract infection (URTI) incidence between treatment and placebo groups.
Alternate: Self-report URTI incidence will be significantly lower in the treatment group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/12/2023, University of Kent SSES Research Ethics and Advisory Group (University of Kent, Chipperfield Building, Park Wood Road, Canterbury, CT2 7PE, United Kingdom; +44 (0) 1227 816940; s.a.smith-75@kent.ac.uk), ref: Proposal 40_20_23

Study design
Double-blind placebo-controlled randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Upper respiratory tract infection (URTI) in healthy, active people

Interventions
Prior to starting the study, all participants will be required to complete a health questionnaire to ensure they are suitable for participation. They will also be required to provide written informed consent.

Randomisation will be performed with computerised randomisation software. Treatment will be administered double-blind with allocation concealment managed by the product manufacturing plant, not directly involved with the study. All researchers involved with the study will remain blinded throughout the duration of the study. The ratio of randomisation between treatment and placebo will be 1:1. The randomisation list will be concealed from investigational sites and stored under lock and key until database closure. Both investigational supplements will have the same macronutrient profile and a similar flavour.

Participants will consume 40g of either a whey protein concentrate (treatment) or a pea protein concentrate (placebo) daily for 12 weeks.

The primary outcome measure will be self-report URTI symptoms, as measured using the Jackson common cold questionnaire, completed daily throughout the monitoring period. If participants do experience any URTI episodes/symptoms, they will be asked to take a swab from the throat and nose for later analysis (to screen for URTI-causing pathogens). Participants will also be asked to visit the laboratory every four weeks (weeks 0, 4, 8 and 12) to complete the Cohen-Hoberman Inventory of Physical Symptoms (CHIPS) questionnaire and to provide blood and saliva samples for the analysis of immune biomarkers.

Intervention Type
Supplement

Primary outcome measure
Number of URTI episodes, recorded using the Jackson common cold questionnaire, completed daily during the 12 weeks and/or by swab-confirmed pathogen detection.

Secondary outcome measures
Current secondary outcome measures as of 01/04/2025:
Participants will visit the laboratory every four weeks (weeks 0, 4, 8 and 12):
1. URTI parameters (symptom duration; severity ratings) recorded using the Jackson common cold questionnaire, completed daily during the 12 weeks
2. URTI episodes with swab-confirmed pathogen detection: participants will be instructed to collect a “self-swab” if they experience a URTI episode (self-reported via Jackson questionnaire). Samples will be screened for the presence of known URTI-causing pathogens using a commercially available respiratory pathogen qPCR panel.
3. Measures of mucosal immunity (secretory IgA and antimicrobial peptides/proteins) will be determined by ELISA assays in saliva at rest on each laboratory visit.
4. Dairy lipid levels will be assessed by colorimetric coupled enzyme assay and/or NMR in blood samples obtained at rest on each laboratory visit.
5. Participants' overall well-being will be assessed using the Cohen-Hoberman Inventory of Physical Symptoms.

Previous secondary outcome measures:
Participants will visit the laboratory every four weeks (weeks 0, 4, 8 and 12):
1. URTI parameters (symptom duration; severity ratings) recorded using the Jackson common cold questionnaire, completed daily during the 12 weeks
2. URTI episodes with swab-confirmed pathogen detection: participants will be instructed to collect a “self-swab” if they experience a URTI episode (self-reported via Jackson questionnaire). Samples will be screened for the presence of known URTI-causing pathogens using a commercially available respiratory pathogen qPCR panel.
3. Immune cell function will be measured in immune cells in/from whole blood samples by

emitted light analysis at rest on each laboratory visit.
4. Measures of mucosal immunity (secretory IgA and antimicrobial peptides/proteins) will be determined by ELISA assays in saliva at rest on each laboratory visit.
5. Stress hormone and cytokine levels will be measured by ELISA in blood samples obtained at rest on each laboratory visit.
6. Dairy lipid levels will be assessed by colorimetric coupled enzyme assay and/or NMR in blood samples obtained at rest on each laboratory visit.
7. Participants will be tested for Epstein-Barr Virus (EBV) serostatus by screening for the presence of the EBV viral capsid antigen IgG (by ELISA) in serum. This will be done on one resting sample from the beginning of each study arm. EBV DNA levels will be determined in all saliva samples by qPCR.
8. Participants' overall well-being will be assessed using the Cohen-Hoberman Inventory of Physical Symptoms.
9. I-FABP concentration will be measured by ELISA assays in blood samples taken at rest on all trials.
10. Bacterial load will be measured via qPCR on blood samples taken at rest on all trials.

Overall study start date
27/08/2023

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. 18+ years old
2. Free from any injury or illness (no URTI within the last 4 weeks)
3. Deemed healthy via a pre-screening health questionnaire
4. No allergies or intolerances to dairy, pea or any other ingredients used in the investigational supplements

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Total final enrolment
115

Key exclusion criteria
1. Under 18 years old
2. Those with current injuries or illnesses (URTI within the last 4 weeks)
3. Those deemed not 'healthy' via a pre-screening health questionnaire
4. Those with allergies and/or intolerances to dairy, pea or any other ingredients used in the investigational supplements

Date of first enrolment
18/12/2023

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Kent
Chipperfield Building
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Sponsor information

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Sponsor type
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ROR
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Funder(s)

Funder type
Industry

Funder Name
Volac International Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The data generated during this study will be available upon request from Will Searle (ws215@kent.ac.uk), Professor Glen Davison (G.Davison@kent.ac.uk) or Dr Megan Judge (M.L. Judge@kent.ac.uk) after completion and publication of study results (de-identified participant data), and may be used for secondary analysis or as part of meta-analyses and other relevant and legitimate scientific uses only. All data will be fully anonymised so that it will not be possible for the identity of participants to be known or deduced. The researchers will ask those requesting data sharing to provide a brief research proposal on how they wish to use the data. This will then form the basis of a data-sharing agreement (if necessary/appropriate to do so), which will clearly detail the criteria for data access and conditions for research use. The researchers will also include a requirement for due acknowledgement and/or co-authorship (if/when appropriate) and acknowledgement of the funder for supporting the original study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/12/2023	No	Yes