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The effects of dairy-based protein supplementation on immunity following exercise

Submission date 11/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/05/2023	**Overall study status** Completed	
Last Edited 12/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Upper respiratory tract infections (URTI) are among the most common illnesses in athletes. Whilst moderate amounts of exercise are accepted to enhance immune function and reduce URTI risk, strenuous prolonged exercise has been shown to increase the chances of picking up some types of infection among athletes. URTIs may affect performance both directly (if suffered during/near competition) or indirectly (impeding training). Therefore, methods to alleviate and lower this risk are of interest. Treatments such as elevated protein diets and milk-based products such as bovine colostrum have been shown to enhance immunity and reduce URTI incidence and/or severity in athletes. Therefore, the present study will investigate the effects of dairy-based protein supplementation on immune function and URTI symptoms/incidence in athletes following prolonged exercise.

Who can participate?:
Healthy volunteers over the age of 18 years who are free from any injury, illness or disease (cardiovascular, metabolic etc). Participants must also be free from any respiratory conditions, such as asthma or exercise-induced bronchoconstriction, and must be deemed ‘healthy’ via a pre-screening health questionnaire, with no allergies or intolerances to dairy or soy. Participants must be experienced with long-duration cycling, being able to complete a 3-hour cycling bout on three consecutive days.

What does the study involve?
Participants will visit the laboratory on ten separate occasions: two visits for ‘preliminary measures’ (VO2max test), two familiarisation visits and six experimental trials. Participants will be randomly assigned to one of two groups, either placebo (PLA) supplementation or whey protein concentrate (WPC) supplementation. Supplements will be taken for 14 days before the experimental trials begin and continued throughout the duration of the experimental trials. For each participant, there will be a 14-day washout period before completing the second crossover arm with the other supplement. The preliminary measures visits will consist of a VO2max test. The familiarisation and experimental trials will consist of a 3-hour cycling bout at a moderate intensity. Blood samples will be taken from a vein near the elbow crease. These samples will be

taken once at preliminary measures trials and multiple times (i.e. before and after exercise) on experimental trials 1, 3, 4 and 6. Saliva samples will be collected on both preliminary measures trials and all experimental trials. For those unable to commit to the entire 3-day repeated main trial protocol, an alternative protocol with only a single main trial per study arm will be offered.

What are the possible benefits and risks of participating?
Participants will receive information on their fitness levels (i.e. VO2max test), which is usually a service that athletes might pay for. They will be provided with reasonable expenses so that they are not left out of pocket by taking part.
The 3-hour cycling bout may cause some delayed onset of muscle soreness. Blood samples may cause minor pain and distress for some participants and there is a minor risk of infection. 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. All exercise and physical activity has a risk of cardiac emergency or injury; for those without underlying heart disease, the risks to health are extremely low. Pre-screening will be used to exclude anybody for whom risk may be elevated above normal. Persons trained in CPR and with access to a defibrillator device will be on hand during all testing.

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

When is the study starting and how long is it expected to run for?
October 2022 to September 2025

Who is funding the study?
1. University of Kent (UK)
2. Volac International Ltd (UK)

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

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UoK SSES REAG Ref No. 26_20_23

Study information

Scientific Title
The effects of dairy-based protein supplementation on immune function and infection risk following exercise

Study objectives
1. Dairy-based protein supplementation will enhance immune function in athletes
2. Dairy-based protein supplementation will reduce upper respiratory tract infection (URTI) incidence following exercise

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2023, University of Kent SSES Research Ethics and Advisory Group (University Of Kent, Chipperfield Building, Park Wood Road, Canterbury, CT2 7PE, UK; +44 (0)1227 816940; s.a.smith-75@kent.ac.uk), ref: Prop 26_20_22

Study design
Single-centre double-blind placebo-controlled randomized crossover study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Maintenance or enhancement of immune function following exercise in healthy adults

Interventions
Randomisation will be performed with computerised randomisation software. Treatment will be administered double-blind with allocation concealment managed by a third-party staff member not involved with the study.

In a double-blind, randomised order, participants will consume a whey protein concentrate (WPC; 40 g/day) or a placebo (40 g/day soy protein), replicating the macronutrient profile of the

WPC. During the first crossover arm, participants will consume their designated supplement daily for 14 days and continue throughout the experimental trials, totalling 17 days. Participants will undergo a 2-week washout period between crossover arms, not consuming anything. Following the washout period, the second crossover arm will replicate the procedures used in the first arm, using the opposing supplement.

Intervention Type
Supplement

Primary outcome(s)
1. Immune cell function will be measured in immune cells in/from whole blood samples by emitted light analysis at rest on preliminary trial days, and pre-, immediately post- and 1 h post-exercise on main trial days 1 and 3 of each study arm
2. Measures of mucosal immunity (secretory IgA and antimicrobial peptides/proteins) will be determined by ELISA assays in saliva at rest on preliminary trial days, and pre-, immediately post- and 1 h post-exercise on main trial days 1, 2 and 3 of each study arm

Key secondary outcome(s))
Current secondary outcome measures as of 25/02/2025:
1. Gut cell damage will be assessed by plasma iFABP levels by ELISA from blood samples obtained pre-, immediately post- and 1 h post-exercise on main trial days 1 and 3 of each study arm
2. Stress hormone will be measured by ELISA in blood samples obtained pre-, immediately post- and 1 h post-exercise on main trial days 1 and 3 of each study arm
3. Dairy lipid levels will be assessed by colorimetric coupled enzyme assay and/or NMR spectroscopy in blood samples obtained at rest (i.e. pre-exercise) on preliminary trial days and on main trial day 1 of each study arm
4. URTI incidence/symptoms will be measured using a daily self-report illness questionnaire (Jackson Common Cold Questionnaire) over the duration of the study
5. If participants believe they are ill, they will be asked to collect throat and nasal swab samples. These samples will be screened for the presence of known URTI-causing pathogens by qPCR.
6. In all experimental trials, participants will complete the state aspect of the State-Trait Anxiety Inventory (STAI-S) and Perceived Stress Scale prior to exercise
7. Participants will complete the Cohen-Hoberman Inventory of Physical Symptoms on experimental trials 1 and 4.
8. Bacterial load will be measured via qPCR on blood samples taken pre-exercise, post-exercise and 1-hour post-exercise on experimental trials 1, 3, 4 and 6.

Previous secondary outcome measures:
1. Gut cell damage will be assessed by plasma iFABP levels by ELISA from blood samples obtained pre-, immediately post- and 1 h post-exercise on main trial days 1 and 3 of each study arm
2. Stress hormone and cytokine levels will be measured by ELISA in blood samples obtained pre-, immediately post- and 1 h post-exercise on main trial days 1 and 3 of each study arm
3. Dairy lipid levels will be assessed by colorimetric coupled enzyme assay in blood samples obtained at rest (i.e. pre-exercise) on preliminary trial days and on main trial days 1 and 3 of each study arm
4. URTI incidence/symptoms will be measured using a daily self-report illness questionnaire (Jackson Common Cold Questionnaire) over the duration of the study
5. If participants believe they are ill, they will be asked to collect throat and nasal swab samples. These samples will be screened for the presence of known URTI-causing pathogens by qPCR.

6. In all experimental trials, participants will complete the state aspect of the State-Trait Anxiety Inventory (STAI-S) and Perceived Stress Scale prior to exercise
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.
Added 04/12/2023:
8. Participants will complete the Cohen-Hoberman Inventory of Physical Symptoms on experimental trials 1 and 4.
Added 04/04/2024:
9. Bacterial load will be measured via qPCR on blood samples taken pre-exercise, post-exercise and 1-hour post-exercise on experimental trials 1, 3, 4 and 6.

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Free from any injury, illness (no illness within 2 weeks) or disease
3. Free from any respiratory conditions (e.g. asthma)
4. Deemed healthy via a pre-screening health questionnaire
5. Experienced with long-duration cycling
6. Have no allergies or intolerances to dairy or soy

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. Under 18 years old
2. Current injuries, illnesses or diseases
3. Asthmatics

4. Not deemed 'healthy' via a pre-screening health questionnaire
5. Inexperienced with long-duration cycling
6. Allergic or intolerant to dairy or soy

Date of first enrolment
24/05/2023

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Kent
Chipperfield Building
Park Wood Road
Canterbury
United Kingdom
CT2 7PE

Sponsor information

Organisation
University of Kent

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
Industry

Funder Name
Volac International Ltd

Funder Name
University of Kent

Alternative Name(s)
The University of Kent

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data generated during this study will be available upon request from Will Searle (ws215@kent.ac.uk) or Glen Davison (G.Davison@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	Participant information sheet	11/11/2025	11/11/2025	No	Yes