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The effect of lycopene on semen quality in healthy men

Submission date	Recruitment status
10/06/2016	No longer recruiting
Registration date	**Overall study status**
16/06/2016	Completed
Last Edited	**Condition category**
10/10/2019	Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lycopene is a naturally occurring carotenoid (nutritional compound) found in a number of foods, such as tomatoes, watermelon and pink grapefruit. Lycopene has antioxidant properties and can protect against damage to cells. Studies have shown that lycopene reduces the risk of prostate cancer and is thought to have more general benefits to men's health including sperm quality. This study aims to investigate the effect of lactolycopene on semen quality in healthy men.

Who can participate?
Healthy male volunteers between the ages of 18-30

What does the study involve?
Participants are invited to attend the Clinical Research Facility, Royal Hallamshire Hospital, Sheffield on three occasions (week 0, 6 and 12). On each occasion they are asked to produce a semen sample at home (after three days of sexual abstinence) to bring with them to the clinic. At the clinic, a blood sample is collected from each volunteer to analyse blood levels of lycopene. At the start of the study data is collected on weight, height, diet, smoking and type of underwear worn. At the 1st visit participants are randomly allocated to receive either a placebo (dummy) tablet or lactolycopene in capsule form and are instructed to consume the capsules twice daily for 12 weeks while following their normal diet. The lactolycopene supplement is a commercially available product available from a range of UK retailers and pharmacists. The supplement is manufactured by Cambridge Nutraceuticals Ltd., UK who are providing the supplement and the placebo for this study. Participants are asked to provide semen and blood samples at the start of the study, week 6 and at the end of the intervention (week 12). Each semen sample is examined for sperm volume, concentration, sperm motility (movement) and morphology (shape). Damage to the DNA of the sperm is also assessed. Blood samples are used to analyse blood lycopene levels as a marker of compliance to the intervention. Participants' diet is analysed at the start of the study and in the final week of intervention using nutritional software. No information is passed back to the donors about semen quality. Participants are reimbursed £25 per clinic visit to compensate them for their time and to cover any travel expenses.

What are the possible benefits & risks of participating?
Participants gain no direct benefit from involvement in the study, but it is hoped that the study will increase our understanding of the relationship between diet and sperm quality. We hope that in future this knowledge will help us with the treatment of male infertility. Blood samples are taken by an experienced phlebotomist in the Clinical Research Facility of a major teaching hospital. Participants may experience some bruising as a result of having the blood sample taken, but we do not anticipate any other risks.

Where is the study run from?
The project will be carried out in the Academic Unit of Reproductive and Developmental Medicine and the Human Nutrition Unit, Department of Oncology and Metabolism, The University of Sheffield, UK. Face to face contact with volunteers will be within the Clinical Research Facility of the Royal Hallamshire Hospital, Sheffield, UK.

Who is funding the study?
The study is self-funded from the University of Sheffield and is being run as part of postgraduate student research projects. Cambridge Nutraceuticals Ltd will supply the supplement and placebo in kind and will also provide participant compensation.

When is the study starting and how long is it expected to run for?
April 2016 to December 2016

Who is the main contact?
Dr Liz Williams
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Contact information

Type(s)
Scientific

Contact name
Dr Liz Williams

ORCID ID
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Contact details
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Beech Hill Road
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S10 2RX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
147769

Study information

Scientific Title
The effect of lactolycopene on sperm quality in healthy men - a pilot study

Acronym
TomsTrial

Study objectives
It is hypothesised that dietary supplementation with lactolycopene will improve semen quality in healthy males.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical School, University of Sheffield Research Ethics Committee, 22/03/2016, Ref: 008135

Study design
12-week double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Effect of lactolycopene on sperm health

Interventions
Participants are randomised to receive either twice daily supplementation with 7mg lactolycopene (i.e. 14mg/d) or a placebo of identically packaged microcrystalline cellulose, twice daily for 12 weeks. Participants are block randomised in blocks of 6.

Intervention Type
Supplement

Primary outcome measure
Motile sperm concentration - assessed at week 0 (baseline), week 6 (interim) and week 12 (end of intervention) according to WHO (2010) methods

Secondary outcome measures
1. Sperm volume, sperm concentration, sperm motility and sperm morphology - analysed according to WHO (2010) methods
2. Sperm DNA fragmentation analysed using the TUNEL assay (Sharma et al. 2013)
3. Sperm DNA fragmentation analysed using the sperm chromatin dispersion test (Fernandez et al. 2003)
4. Plasma lycopene measured by HPLC (Thurnham et al. 1988)
The above outcomes will be measured at week 0 (baseline), week 6 (interim) and week 12 (end of intervention)

5. Dietary intake - measured using an 4-day estimated food diary at week 0 and during week 12 and analysed using WinDiets dietary analysis software
6. Habitual dietary intake - assessed at baseline only - using EPIC food frequency questionnaire, and analysed using FETA-EPIC software (http://www.epic-norfolk.org.uk/)

Overall study start date
11/04/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Healthy males
2. Age 18-30

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Male

Target number of participants

60

Total final enrolment
60

Key exclusion criteria
1. Previous testicular surgery
2. Treatment for cancer
3. Current consumption of lycopene supplements
4. Allergy to tomato, whey protein or soy derivatives

Date of first enrolment
29/04/2016

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
United Kingdom

United States of America

Study participating centre
The University of Sheffield
Department of Oncology & Metabolism
Beech Hill Road
Sheffield
United States of America
S10 2RX

Sponsor information

Organisation
The University of Sheffield (UK)

Sponsor details
Research & Innovation Services
New Spring House
231 Glossop Road
Sheffield
England
United Kingdom
S10 2GW

Sponsor type
University/education

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
University/education

Funder Name
University of Sheffield

Alternative Name(s)
sheffielduni, University of Sheffield UK, theuniversityofsheffield, University of Sheffield in United Kingdom, University of Sheffield, UK, The University of Sheffield, Sheffield University

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Cambridge Nutraceuticals Ltd (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2020	10/10/2019	Yes	No