

A study of the effects of the FertilMate - a Scrotal COoling Patch on male fertility (SCOP)

Submission date 15/07/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 29/09/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/11/2018	Condition category Urological and Genital Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The testes are housed in the scrotum because the scrotum is a few degrees cooler than the core body temperature, which forms the best environment for sperm production. This study aims to find out whether exposing the scrotum to lower temperatures using a cooling patch improves the fertility of men who have abnormal sperm counts.

Who can participate?

Any man above the age of 18 who has an abnormal sperm count.

What does the study involve?

Participants are randomly allocated to one of two groups. Men in one group wear the cooling patch for 8 hours per day for a period of 90 consecutive days. Men in the other group do not wear the patch. In order to determine if there is an improvement we test the participants' sperm count at the start and the end of the study.

What are the possible benefits and risks of participating?

To date we do not know of any risks as the cooling patch has been tested and proven to be safe.

Where is the study run from?

Nottingham University Hospitals (UK).

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

August 2011 to May 2012.

Who is funding the study?

University of Nottingham (UK).

Who is the main contact?

Mr William Atiomo (william.atiomo@nottingham.ac.uk)

Dr Ilias Nikolopoulos (illias.nikolopolous@nuh.nhs.uk)

Dr Waseem Osman (Mohammed.Osman@nuh.nhs.uk)

Contact information

Type(s)

Scientific

Contact name

Mr William Atiomo

Contact details

Nottingham University Hospitals
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Additional identifiers

Protocol serial number

EM 11024

Study information

Scientific Title

A pilot randomised study of the effects of the FertilMate - a scrotal cooling patch on male fertility

Acronym

SCOP

Study objectives

To determine whether exposing the scrotum to lower temperatures by means of a scrotal cooling patch may improve fertility.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands - Nottingham 2, 27/05/2011, ref: 11/EM/0163

Primary study design

Interventional

Study design

Randomised control trial pilot study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Reproductive medicine

Interventions

1. Scrotal cooling patch worn by the study group
2. Semen analyses on all 40 participants on day 0 and day 90
3. Serum metabolomics tested by means of 1x 20ml blood sample

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. To determine whether exposing the scrotum to lower temperatures by means of a scrotal cooling patch may improve fertility
2. The main parameter will be a change to sperm count, quality and concentration
3. Improvements to sperm motility and morphology

Key secondary outcome(s)

Scrotal bloodflow

Completion date

01/05/2012

Eligibility**Key inclusion criteria**

1. Males
2. Aged 18 to 45 years of age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Key exclusion criteria

1. Candidates who have undergone a vasectomy
2. Candidates who have an allergy to menthol

3. Males aged below 18 and older than 45 years on age
4. We will not be recruiting individuals that are unable to consent for themselves and nor will we be including participants who are from vulnerable groups

Date of first enrolment

01/08/2011

Date of final enrolment

01/05/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Nottingham University Hospitals

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

University/education

Funder Name

University of Nottingham (UK)

Alternative Name(s)

The University of Nottingham

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/04/2012		Yes	No