

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

<b>Submission date</b> 15/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/11/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:william.atiomo@nottingham.ac.uk))

Dr Ilias Nikolopoulos ([illias.nikolopolous@nuh.nhs.uk](mailto:illias.nikolopolous@nuh.nhs.uk))

Dr Waseem Osman ([Mohammed.Osman@nuh.nhs.uk](mailto: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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Study design

Randomised control trial pilot study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**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 measure**

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

**Secondary outcome measures**

Scrotal bloodflow

**Overall study start date**

01/08/2011

**Completion date**

01/05/2012

**Eligibility****Key inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

40, 20 in the study group and 20 in the control group

**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**

England

United Kingdom

**Study participating centre**

Nottingham University Hospitals

Nottingham

United Kingdom

NG7 2UH

**Sponsor information****Organisation**

University of Nottingham (UK)

**Sponsor details**

c/o Mr Paul Cartledge  
University of Nottingham  
University Park  
Nottingham  
United Kingdom  
NG7 2 RD

**Sponsor type**

University/education

**Website**

<http://www.nottingham.ac.uk/>

**ROR**

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

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Nottingham (UK)

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	27/04/2012		Yes	No