ISRCTN57825419 https://doi.org/10.1186/ISRCTN57825419

Manchester Adolescent Varicocele Study

Submission date
27/10/2011

Recruitment status
No longer recruiting

Registration date
24/11/2011

Overall study status
Completed

Last Edited
27/01/2026

Condition category
Urological and Genital Diseases

[_] 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
Varicoceles are dilated veins around the scrotum and are commonly associated with infertility in men. Current international guidelines suggest that boys with varicoceles should undergo surgery only if their testicle is not growing properly or if the varicocele is causing pain. However, following these guidelines can result in reduced fertility in adult life, as has been shown in a recent paper. At the moment the usual care for boys who have a varicocele and normal size of testicles is not to perform surgery. We would like to find out if early varicocele surgery is better than waiting until the testicle stops growing.

Who can participate?
The study is for boys aged 14 to 17 years old with a varicocele where the blood flow in the varicocele is spontaneous and the size of each testicle is symmetrical. Patients must also not have had groin surgery, an inflamed epididymis and or problems with hormone levels as these can affect fertility and may affect the results of the study.

What does the study involve?
Patients with a varicocele and normal sized testicles, will be randomly put into groups. The first group will follow the current guidelines and receive conservative treatment (no surgery). The second group will receive early surgery.
Following parents' permission, the GP will be informed of the boy's participation in the study. Each patient will be asked to produce a semen sample at the start and end of the study. This is essential to allow us to find out if surgery affects semen quality. This will also pick up problems with fertility early and allow plans to be made in advance.
Varicocele surgery will be done under a general anaesthetic and involves tying off the dilated veins. It can be done as a day-case. The exact operation depends on which veins are leaking on the Doppler ultrasound scan. It is done using a key-hole surgery or with an incision in the groin.

What are the possible benefits and risks of participating?
This study has the potential to help us find out if early surgery in children with varicocele improves fertility. Participants will be carefully monitored for their condition by a team of specialists in this field until they are18 years of age. Sperm banking will be offered for free.
If the patient does not get allocated early surgery, he will be regularly reviewed in our clinic where we will check on the growth of the testicle. This is current standard management for varicoceles, which are not painful or do not affect the size of the testicle. If either of these

conditions develop or the initial semen analysis shows a problem with the sperm quality, he will be treated with an operation as current guidelines recommend.
Generally the surgery is very safe and effective. The specific risks of varicocele surgery include: wound infection and bleeding (rare), some fluid can develop around the testicle (10-15% although the majority go away spontaneously) and there will be a scar.

Where is the study run from?
The study is run by Mr Keene (Registrar Paediatric Surgery) and Mr Cervellione (Consultant Paediatric Urologist) based at the Royal Manchester Childrens Hospital.

When is the study starting and how long is it expected to run for?
The study is expected to start in April 2011 and to last 4 years.

Who is funding the study?
The Central Manchester Foundation NHS Trust Urological Charitable Research Fund

Who is the main contact?
Mr David Keene
dkeene@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mr David Keene

Contact details
Department of Paediatric Urology
Royal Manchester Children's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
R00409

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R00732

Study information

Scientific Title
Open randomised control study to assess the impact on fertility of early surgery in adolescents with varicocele

Acronym
MAVS

Study objectives
Current international urology guidelines for adolescents state that varicocele surgery should be undertaken if there is growth arrest of the testicle or if the varicocele is painful.

If these guidelines are followed a recent study shows that at 18 years of age many of these men have poor semen quality.

Our study aims to investigate if earlier surgery, before growth arrest occurs, improves fertility. Some studies have been done in adults showing that repair of varicoceles can improve semen analysis, however no similar work has been done in adolescents. Testicular ultrasound has been shown to be an accurate way to assess testicular volume. In our study we plan to use ultrasound to monitor testicular growth. Unusual shaped sperms, poor movement and lower sperm numbers are the commonest findings on semen analysis in men with varicocele related infertility. The trial aims to see if some of these abnormalities are prevented by early surgery.

Our hypothesis: If varicocele surgery is performed in adolescents before testicular growth is affected, fertility will be preserved.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tameside and Glossop Regional Ethics Committee approved on 17/03/2009, ref 09/H1013/15

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Varicocele

Interventions
All patients referred with a varicocele, will be examined by a consultant paediatric urologist to assess the pubertal stage and the severity of the varicocele.

A doppler ultrasound will be performed during spontaneous breathing and under Valsalva manoevre to assess the severity of reflux (flow of blood in the dilated veins), and to identify which veins this is occuring in. Testicular ultrasound using electronic calipers will be used to measure testicular size and testicular volume will be estimated.

Patients with grade 2 and 3 clinical varicoceles with continuous venous reflux on doppler ultrasound without evidence significant testicular growth arrest will be candidates for the study. Testicular growth arrest is defined as testicular volume at least 20% smaller than the contralateral testicle.

Surgery or non surgical treatment will be randomly allocated to each patient. This will be done by an independent third party using a computer generated spreadsheet. The exact operation (either groin surgery or a keyhole approach) will be determined by the findings on the doppler ultrasound scan. If the reflux occurs only in the testicular veins then key hole surgery would be done, otherwise a groin approach would be used.

In both groups follow up will be done every 6 months with clinical examination, testicular ultrasound and doppler. The patient's symptoms, grade of varicocele and testicular volumes will be recorded. In the surgical group postop complications will also be recorded.

Any patient in the conservative group who develops testicular growth arrest will be treated surgically as recommended by the current guidelines. They will remain in the conservative group for analysis on an intention to treat basis.

All patients will be followed up post study and referred to an adult urologist if appropriate.

Intervention Type
Other

Primary outcome(s)
To compare the trend in semen analysis between the two groups:
1. Percentage normal semen quality (according to the WHO criteria)
2. Percentage of motile sperm
3. Mean concentration of sperm (million per millilitre)

Key secondary outcome(s))
Difference in testicular volume (ml) between the affected side (with the varicocele) and the contralateral testis. The testicular sizes will be measured every 6 months.

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Between ages of 14-17 years at recruitment to study
2. Have a clinically detectable varicocele
3. High grade reflux on Doppler ultrasound (grade 2 or 3)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
14 years

Upper age limit
17 years

Sex
Male

Total final enrolment
93

Key exclusion criteria
1. Children younger than 14 years of age or older than 17 years at time of recruitment to study
2. Testicular growth arrest
3. Previous inguinal surgery
4. Orchitis
5. Epididymo-orchitis
6. Testicular torsion
7. Endocrinological disorders

Date of first enrolment
01/04/2011

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Paediatric Urology
-
Manchester
England
M13 9WL

Sponsor information

Organisation
Central Manchester Foundation NHS Trust (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Central Manchester Foundation NHS Trust (UK) - Urological Charitable Research Fund (ref: 629826)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes