ISRCTN92614042 https://doi.org/10.1186/ISRCTN92614042

Is ICG imaging safe and accurate to predict testicular torsion?

Submission date	Recruitment status	[_] Prospectively registered
21/07/2023	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/12/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/01/2024	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Testicular torsion is a time critical condition for children and young people. It is difficult to diagnose without an operation. Missing it means the child will lose a testicle. There are no good diagnostic tests, only tests that delay the child's journey to theatre, which puts them at further risk of losing the testicle. Most boys with a painful testicle get a surgical exploration to see if it is torsion and to untwist and fix it. Up to 85% of children having surgery will not have torsion. They will have something they didn't need surgery for. We want to see whether a new, low risk, fast investigation could be used to diagnose the problem, meaning no torsions are missed and less children have unnecessary surgery. This study will test ICG which is a fluorescent dye which shows flow or lack of flow in an organ. The researchers hope it will be able to show the testes with absent blood flow to diagnose torsion, so no boys lose a testis in future. They hope it will show when there is a good blood supply preventing many hundreds of young men a year having an unnecessary operation.

Who can participate?
Children aged 0-19 years presenting with testicular pain being taken to theatre for scrotal exploration at Sheffield Children's NHS Foundation Trust

What does the study involve?
When it is decided a child needs to go to theatre for a painful scrotum the researchers will take a specialist camera photo after giving the dye (with no radiation exposure) and compare the findings of the photo with the outcome at surgery. This will allow them to test if it is safe and accurate.

What are the possible benefits and risks of participating?
The possible benefits of the dye and camera system are huge. The study is going to investigate whether ICG dye can safely diagnose torsion in a protocol which affects the child's normal pathway minimally and exposes them to almost no additional risk. The side effects of ICG angiography in children, not under general anaesthetic, include nausea and vomiting (19%), itchy skin (2%), hot flush (2%), bronchial spasm (3%). In a larger meta-analysis no severe adverse reactions were described. The risks are similar to the risks of CT contrast use reported at 1 /42000 for an anaphylactic reaction. Use of ICG should be avoided in those with previous

anaphylactic reactions. Similarly, ICG injection contains iodine and should be avoided with those with a iodine allergy. If an adverse reaction rate to ICG injection of over 3 % is noted the study will be abandoned. The anesthetist will be slowly monitoring the child as standard during surgery and rapid intervention will proceed.

Where is the study run from?
Sheffield Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2023 to September 2025

Who is funding the study?
The Children's Hospital Charity (UK)

Who is the main contact?
Dr Caroline MacDonald, carolinemary.macdonald@nhs.net

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Ms Caroline MacDonald

Contact details
D Floor
Damer Street
Western Bank
Sheffield
United Kingdom
S10 2TH
-
carolinemary.macdonald@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008108

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SCH-2769, IRAS 1008108

Study information

Scientific Title
Assessment of diagnostic accuracy of indocyanine green fluorescence imaging in children and young people with testicular pain requiring surgical exploration

Acronym
ICG in Paediatric Acute Scrotum

Study objectives
Primary objective:
To calculate the diagnostic accuracy of torsion versus non-torsion for CYP presenting with acute scrotum who are undergoing scrotal exploration

Secondary objectives:
1. To calculate the diagnostic value of ICG by skin type and tanner stage
2. To calculate the diagnostic value of ICG post detorsion for predicting long-term testicular loss
3. To explore patient and family acceptability of ICG imaging without sedation or GA in the emergency department setting for testicular pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/11/2023, West Midlands - Coventry & Warwickshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; 02071048211; coventryandwarwick.rec@hra.nhs.uk), ref: 23/WM/0179

Study design
Single-centre interventional controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Safety

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

Health condition(s) or problem(s) studied
Acute scrotum

Interventions

One intervention for this study, an intravenous injection of indocyanine green into the scrotum. Then utilising a specialist near infra-red (NIR) camera, an image of the CYP scrotum will be captured. The participant will then receive their normal routine care. After 1 year, there will be a follow-up visit with the CI.

Intervention Type
Drug

Pharmaceutical study type(s)
Diagnosis

Phase
Phase II

Drug/device/biological/vaccine name(s)
Indocyanine green fluorescent dye

Primary outcome measure
Diagnostic accuracy of ICG for testicular torsion as compared to non-torsion diagnosis, will be calculated by findings of fluorescence versus non-fluorescence compared to surgical outcomes of salvage versus non salvage at surgery

Secondary outcome measures
1. ICG diagnostic accuracy by tanner stage and skin pigmentation will be calculated by findings of fluorescence versus non-fluorescence compared to surgical outcomes of salvage versus non salvage at surgery
2. ICG to predict late testicular atrophy will be calculated by findings of fluorescence versus non-fluorescence compared to surgical outcomes of salvage versus non salvage at 12 month clinical review
3. Adverse reactions from ICG injection measured using SUSAR reporting for inpatient course
4. Family and CYP acceptance of diagnostic procedure measured using survey and qualitative methodology

Overall study start date
19/07/2023

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Children presenting with testicular pain being taken to theatre for scrotal exploration at Sheffield Children's NHS Foundation Trust
2. Aged 0-19 years

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
19 Years

Sex
Male

Target number of participants
107

Key exclusion criteria
Children with any allergy to contrast medium or iodine

Date of first enrolment
30/07/2023

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Sheffield Children's NHS Foundation Trust

Sponsor details
Western Bank
Sheffield
England

United Kingdom
S6 5DA
+44 (0)114 2717417
scn-tr.research.governance@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.sheffieldchildrens.nhs.uk/

ROR
https://ror.org/02md8hv62

Funder(s)

Funder type
Charity

Funder Name
The Children's Hospital Charity

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Conference presentation
3. Publication on website
4. Submission to regulatory authorities

The sharing of data will be in line with GCP and GDPR. Only accessible on NHS and University VPN. Appropriate data sharing agreements will be agreed upon before opening of the trial. The data will be kept on NHS VPN and available for audit. Data can be made available anonymised via Mendeley Dataset.

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date