

Guy's and St Thomas' Paediatric Thrombosis Registry

Submission date 31/03/2010	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2010	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/03/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Thrombosis occurs when a blood clot forms inside a blood vessel and obstructs the flow of blood. The aim of this study is to collect data on thrombosis occurring in patients aged under 18 (neonatal and paediatric thrombosis).

Who can participate?

Children (under 18 years of age) who have been diagnosed with thrombosis

What does the study involve?

We collect clinical and routine laboratory data on patients with thrombosis. No additional investigation is required and all tests performed are part of the patient's normal diagnostic analysis.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

St Thomas' Hospital (UK)

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

May 2010 to May 2050

Who is funding the study?

Sanofi Aventis (UK)

Who is the main contact?

Dr Jayanthi Alamelu

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Contact information

Type(s)

Scientific

Contact name

Dr Jayanthi Alamelu

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Collecting epidemiological and treatment data on neonatal and paediatric thrombosis in the Guy's and St Thomas' Paediatric Thrombosis Registry: a retrospective observational study

Acronym

PaedCLOT

Study objectives

PaedCLOT is a registry to collect epidemiological and treatment data on neonatal and paediatric thrombosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East London REC 2 (formerly St Thomas' REC), 25/05/2010, ref: 10/H0802/36

Study design

Retrospective observational study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Paediatric thrombosis

Interventions

Study design and methodology:

This is a registry requiring the collection of baseline and follow up clinical and routine laboratory data on patients presenting with thrombosis. No additional investigation will be required as part of participation in this registry. All tests performed will be part of the patients normal diagnostic analysis.

Patient population:

Children (under 18 years of age) presenting with thrombosis will be included in the registry. The patients may have had a previous episode of thrombosis or be new cases. All patients will require consent signed by a parent or legal guardian. Patients must have clinically or radiologically identified documented thrombosis.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Determine the incidence, distribution of cases and epidemiology of neonatal and paediatric thrombosis in the UK, measured as timepoint of entry to the registry.

Secondary outcome measures

1. Identifying associated risk factors in paediatric thrombosis
2. Treatment practices currently used
3. Morbidity with outcome data
4. Mortality data

Measured both at the time of entry and follow-up over time in cases that would be otherwise reviewed upto a year or longer if there are any long term complications.

Overall study start date

01/05/2010

Completion date

01/05/2050

Eligibility

Key inclusion criteria

1. Patients with a clinical or radiological diagnosis of thrombosis
2. Aged less than 18 years, either sex
3. Consent for addition to the Registry

Participant type(s)

Patient

Age group

Child

Upper age limit

18 Years

Sex

Both

Target number of participants

1000

Key exclusion criteria

Lack of documented thrombosis

Date of first enrolment

01/05/2010

Date of final enrolment

01/05/2050

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Thomas' Hospital

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Guy's and St. Thomas' NHS Foundation Trust (UK)

Sponsor details

R&D Department
16th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT
+44 (0)20 7188 5736
karen.ignatian@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.guysandstthomas.nhs.uk/>

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Industry

Funder Name

Sanofi Aventis (UK)

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?
HRA research summary			28/06/2023	No	No