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Guy's and St Thomas' Paediatric Thrombosis Registry

Submission date 31/03/2010	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 01/07/2010	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 15/03/2016	**Condition category** Circulatory System	[ ] Individual participant data [ ] 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?
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Contact information

Type(s)

Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

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

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Sanofi Aventis (UK)

Results and Publications

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