

# Guy's and St Thomas' Paediatric Thrombosis Registry

<b>Submission date</b> 31/03/2010	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2010	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/03/2016	<b>Condition category</b> 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  
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## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No