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DRIVE - Desmopressin for procedures or radiological interventions

Submission date
30/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Haematological Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Platelets are the component of blood which helps the blood to clot. People with low platelet counts are vulnerable to bleeding. Approximately one-third of patients in intensive care have a low platelet count and the majority undergo at least one invasive procedure during their time in intensive care. Desmopressin is a medication commonly used for congenital (from birth) bleeding disorders such as haemophilia and von Willebrand disease and it has few side effects. This study aims to assess the feasibility of administering desmopressin to these patients with low platelet counts before they undergo surgery.

Who can participate?
Adults with low platelet counts who are scheduled to have an interventional procedure (a procedure that involves making a cut in the body).

What does the study involve?
Participants are randomly allocated to receive a single dose through drip of either desmopressin or placebo (dummy drug), prior they have their interventional procedure. The surgery is conducted according to standard practice. Blood samples are collected before the treatment and at 30 minutes and 120 minutes after treatment. Participant progress is checked after 24 hours, then at 7 days, and at 28 days after the treatment.

What are the possible benefits and risks of participating?
Administering desmopressin may prevent procedure-related serious bleeding events, but at present it is not known if this will be the case. It has proven to be effective at reducing bleeding for people who are undergoing surgery, but this trial will look at whether it will also work well for Intensive Care patients. Some patients may experience facial flushing (redness in the face), nausea (feeling sick) or stomach pain, or headache. Rarely people will get a low blood pressure during the infusion of desmopressin. Some people may develop low levels of salt (sodium) in their blood after they receive desmopressin. Very rarely (in less than 1 in 10,000 people) desmopressin may cause very low salt levels which can lead to seizures. Very rarely desmopressin could cause an allergic reaction. Participants will be closely monitored for any evidence of these side effects.

Where is the study run from?
NHS Blood and Transplant Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2016 to July 2019

Who is funding the study?
NHS Blood and Transplant (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
2016-001126-33

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 32526

Study information

Scientific Title

A placebo-controlled double-blind, randomised feasibility trial of Desmopressin (DDAVP) in critical illness prior to procedures

Acronym
DRIVE

Study objectives
The aim of this study is to investigate the feasibility of administering desmopressin in intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford C Research Ethics Committee, 29/11/2016, ref: 16/SC/0524

Study design
Randomized; Interventional; Design type: Treatment, Prevention, Drug

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Low platelet count

Interventions
Following the provision of informed consent, participants will be randomised to receive a single intravenous infusion of either desmopressin (0.3 micrograms per kg, made up to 50 ml with saline) or placebo (50 ml saline). All participants will be followed up until Day 28 post-treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Desmopressin

Primary outcome measure
Proportion of eligible patients who are randomised and receive the IMP is assessed by analysis of screening and recruitment data at the end of the study.

Secondary outcome measures
1. Adherence to protocol measured at 28 days post-treatment, measured by analysis of Case Report Forms at the end of the study
2. Time taken to administer IMP (from randomisation), measured by analysis of Case Report Forms at the end of the study
3. Difference in change in percentage aggregation of platelets in microfluidics chamber between desmopressin and placebo before and after IMP, measured by blood tests at pre-treatment, 30 minutes post-treatment and 120 minutes post-treatment
4. Difference in change in PFA-200 closure time for ADP/collagen and P2Y cartridges between desmopressin and placebo before and after IMP, measured by blood tests at pre-treatment, 30 minutes post-treatment and 120 minutes post-treatment
5. Difference in change in thrombin generation, between desmopressin and placebo before and after IMP, measured by blood tests at pre-treatment, 30 minutes post-treatment and 120 minutes post-treatment
6. Bleeding up to 24 hours after administration of IMP, measured using the HEME (Haemorrhage Measurement Tool) Bleeding Assessment at 24 hours
7. Thromboembolic events up to 28 days after administration of IMP, measured by reviewing patient notes at Day 1, Day 7 and Day 28.
8. Exposure to blood products (red cell transfusion, platelet transfusion) up to 24 hours after administration of IMP, measured by reviewing patient notes at Day 1

Overall study start date
01/01/2016

Completion date
04/07/2019

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Platelet count less than or equal to 100 x 10^9/L
3. Inpatient on a critical care ward
4. Due to undergo an invasive procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
40

Key exclusion criteria
1. Active bleeding
2. History of ischaemic heart disease (myocardial infarction or angina), stroke or transient ichaemic attack (TIA)
3. Admission to ICU with traumatic brain injury or seizures
4. Congenital bleeding disorder
5. Pregnant or breastfeeding
6. History of anaphylaxis to desmopressin

Date of first enrolment
31/01/2017

Date of final enrolment
06/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Blood and Transplant Clinical Trials Unit
Long Road
Cambridge
United Kingdom
CB2 0PT

Sponsor information

Organisation
NHS Blood and Transplant

Sponsor details

500 North Bristol Park
Filton
Bristol
England
United Kingdom
BS34 7QH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
NHS Blood and Transplant

Results and Publications

Publication and dissemination plan
Plan to publish the study results in a peer-reviewed journal, as soon as possible following database lock.

Intention to publish date
04/07/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		04/10/2021	06/10/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		16/06/2024	05/02/2025	Yes	No