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Dabigatran Presence in Breast Milk (DALMATION)

Submission date
09/03/2016

Recruitment status
No longer recruiting

Registration date
09/03/2016

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Women who have given birth, especially those who have had a Caesarean section, are at risk of developing deep vein thrombosis (DVT). DVT is where a blood clot develops in a deep vein in one or both of the legs, causing pain, swelling and long term complications such as leg ulcers. In order to avoid this, these women are usually given injections of a drug called heparin (a blood thinner) for up to 7 days after delivery. If a mother is taking heparin, it is considered safe for the baby as it does not pass into breast milk. Most women are discharged before 7 days after delivery and need to continue doing the injections themselves at home. This involves taking the sharps home, and many women find it difficult and inconvenient and there is evidence to suggest that many women do not take the injections at all. Dabigatran is a blood thinning drug that can be swallowed as a hard capsule. It is currently licenced in the UK for other situations including the prevention of blood clots after hip/knee replacement surgery. It is currently not known whether this drug would pass into breast milk after it has been taken by the mother and therefore safe for the baby. The aim of this study is to find out whether dabigatran capsule could be used instead of heparin injections for new mothers by finding out if it passes into breast milk.

Who can participate?
Women who have given birth who have made the decision not to breastfeed their baby.

What does the study involve?
All participants are given two 110mg capsules of dabigatran to take. A total of seven samples of breast milk (15ml each) and blood (15ml) are then taken immediately, 1, 2, 3, 5, 7 and 10 hours after the capsules have been taken. The samples are then tested in the lab in order to find out the amount of dabigatran present in each.

What are the possible benefits and risks of participating?
There are no direct benefits to participants taking part in this study. There is a small risk of pain and discomfort during the taking of blood samples from participants . Additionally, there is a very small risk of bleeding when taking dabigatran, however all participants be in hospital for the treatment visit and extra safety tests will be done before the drug is given in order to avoid complications.

Where is the study run from?
Newcastle Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
February 2016 to August 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Jean Walker

Contact information

Type(s)
Public

Contact name
Miss Jenn Walker

Contact details
Newcastle University
Newcastle Clinical Trials Unit
1-4, Claremont Terrace
Newcastle upon Tyne
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NE2 4AE

Additional identifiers

EudraCT/CTIS number
2014-004249-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20287

Study information

Scientific Title
An Open Label, Non--Randomised, Phase II study to Determine if Dabigatran and its Metabolites are Detectable in Breast Milk Following Oral Administration to Non--Breastfeeding Mothers

Acronym
DALMATION

Study objectives
The aim of this study is to find out if a dabigatran capsule could be used instead of heparin injections to reduce the risk of deep vein thrombosis in new mothers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Tyne & Wear South Research Ethics Committee, 11/11/2015, ref: 15/NE/0331

Study design
Open-label non--randomised phase II study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Children, Reproductive Health; Subtopic: Children (all Diagnoses), Reproductive Health & Childbirth (all Subtopics); Disease: All Diseases, Reproductive Health & Childbirth

Interventions
The study duration is 12 months, including a recruit period of 7 months in which to consent 10 women. All eligible and enrolled women will receive a single oral dose of a 110mg dabigatran capsule, swallowed with water. Participants will be asked to complete a 10 hour treatment visit to provide up to 7 expressed breast milk samples and 7 blood samples. Each participant will be supported by the research midwife and additional support offered from the Infant Feeding Coordinator for up to 2 weeks following expression. The last follow up contact at 2 weeks will be the end of the study for the participants, after which their routine post-natal clinical care will continue.

Intervention Type
Other

Phase
Phase II

Primary outcome measure

Dabigatran presence in plasma and breast milk is measured at baseline, 1, 2, 3, 5, 7, 10 hours.

Secondary outcome measures
1. Presence of dabigatran metabolites in breast milk is measured at baseline, 1, 2, 3, 5, 7, 10 hours
2. Time course of dabigatran concentration in breast milk is measured at baseline, 1, 2, 3, 5, 7, 10 hours
3. Time course of dabigatran concentration in maternal plasma is measured at baseline, 1, 2, 3, 5, 7, 10 hours

Overall study start date
01/12/2014

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Women aged 18 years and over
2. Woman has had a vaginal birth (spontaneous or instrumental)
3. Minimum of 48 hours has passed after delivery of the baby/removal of epidural catheter or spinal anaesthesia
4. Minimum of 24 hours has passed after the decision has been made and documented in the notes to stop breast feeding the baby after starting/trying to start
5. Hospital inpatient
6. Woman has been offered the opportunity to have a discussion at delivery and in the immediate postnatal period in relation to their feeding choices using the Feeding Your Baby booklet
7. Decision has been confirmed by the woman to exclusively formula-feed her baby (including women who have since decided to stop breast-feeding their baby)
8. Midwife has confirmed the decision with the woman and has documented this in the Feeding Your Baby Booklet held in the medical notes.
9. Normal renal function test – results of the serum creatinine <90 micro mol/L
10. Normal liver function tests – results of the serum ALT </= 40 IU/L
11. Not taking any medication except paracetamol and / or dihydrocodeine. Women who have been given ibuprofen for pain relief after delivery can be included at least 24 hours after the last dose. Women will be advised not to take nonsteroidal anti-inflammatory drugs (aspirin, ibuprofen, diclofenac, naproxen, indometnacin) for at least 3 days after taking the study treatment)
12. Participant has provided written informed consent for participation in the study before any study specific procedures take place

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 10; UK Sample Size: 10

Total final enrolment
2

Key exclusion criteria
1. Women who are planning to/are breastfeeding
2. Women who are planning to/giving their baby expressed breast milk
3. Women who are unsure of their decision to breast feed or formula feed
4. Women who are unable to provide written informed consent
5. LMWH thromboprophylaxis is indicated
6. Increased risk of bleeding for any reason
7. An increased tendency to bleed (inborn, of unknown cause or due to other medications)
8. Known contra-indications to dabigatran
9. On-going treatment with aspirin, NSAIDs or other drugs that affect haemostasis
10. Treatment with oral ketoconazole or itraconazole, medicines to treat fungal infections
11. Patients who have received an artificial heart valve, have had a heart attack or suffer an irregular heartbeat (including taking dronedarone)
12. Known impaired renal function (serum creatinine > 90 micro mol/L)
13. Known abnormal liver function tests (ALT > 40 IU/L)
14. Known hypersensitivity or allergy to dabigatran
15. Use of other investigational study drugs within 30 days prior to study entry

Date of first enrolment
27/04/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Clinical Trials Unit
Newcastle University
1-4, Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Royal Victoria Infirmary
Neonatal Service Ward 35
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Boehringer Ingelheim Ltd

Results and Publications

Publication and dissemination plan
Planned publication on the detection of dabigatran and its metabolites in breast milk following single oral dose in non-breastfeeding mothers.

Intention to publish date
31/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/06/2019	No	No
HRA research summary			28/06/2023	No	No