ISRCTN12831121 https://doi.org/10.1186/ISRCTN12831121

Diagnose the red baby

Submission date
13/05/2015

Recruitment status
No longer recruiting

Registration date
04/07/2015

Overall study status
Completed

Last Edited
12/06/2015

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Having a red baby is rare and worldwide we don't know how many red babies are born each year. The redness can be compared to eczema. It's red, scaly but covered all over the body (>90%). There are many possible underlying causes. One of these causes is disruptions in the human defense mechanism and can result in the death of the baby. Because this risk, it is important to get a fast diagnosis. A good treatment can start soon in most cases. We developed a protocol which can be followed by doctors. With this protocol we believe it will be easier to get a diagnosis.

Who can participate?
Every newborn baby with a red skin or young children with a red skin in which a diagnosis could not be found.

What does the study involve?
Each participant is treated by a clinician. They follow a national protocol, including a skin biopsy and a blood sample for a genetic test.

What are the possible benefits and risks of participating?
There are no risks while following the protocol. A skin biopsy is a little painful, but is very short and will not harm the baby. The protocol may result in a fast diagnosis and thus a fast treatment.

Where is the study run from?
The study runs in the Netherlands, with the Erasmus Medical Centre in Rotterdam as the coordinating Centre. Medical Centres as Maastischt University Medical Centre, Radboud University Medical Centre Nijmegen, University Medical Centre Groningen and the University Medical Centre Utrecht are cooperating in the study as well. Patients can however also be recruited out of other hospitals.

When is the study starting and how long is it expected to run for?
September 2014 to September 2016

Who is funding the study?
The study is funded by NutsOhra and Stichting Coolsingel (Rotterdam, the Netherlands).

Who is the main contact?
Prof. Dr. Suzanne G.M.A. Pasmans

Study website
www.huidhuis.nl/afdeling/neonatale-erythrodermie

Contact information

Type(s)
Scientific

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Fast track management of neonatal erythroderma

Study objectives

Faster and accurate diagnoses in neonatal erythroderma using a national multidisciplinary protocol, including genetic evaluation with next generation sequencing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erasmus Medical Centre, Rotterdam, The Netherlands, 08.005/2014, ref: MEC-2014-208

Study design
National prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Newborn with a collodion membrane or congenital erythroderma or erythroderma developed in the first four weeks after birth.

Interventions
A national multidisciplinary protocol with a diagnostic flowchart will be used. Basic diagnostics include basic laboratory investigations, a skin biopsy and 2x3 ml blood for genetic tests. The genetic test is based on a gene panel (51 genes) accoring to all possible diagnoses in erythrodermic newborns.

Intervention Type
Mixed

Primary outcome measure
Clinical characteristics, observed by the clinician, such as erythroderma, collodion membrane, bullae, alopecia etc. These will be measured during first clinical visit. Histological data (skin biopsy) and laboratory findings (normal blood count, total IgE, etc) will be collected. The data for these findings can be different per individual, because not every child/neonate will be seen by a clinician at the same time (e.g. day 1, week 1, etc.).

Secondary outcome measures
Morbidity and mortality

Overall study start date
01/09/2014

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Collodion membrane at birth or
2. Erythroderma at birth or
3. Erythroderma developed in neonatal period (first four weeks postpartum)

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
30

Key exclusion criteria
Erythroderma developed after the first month postpartum

Date of first enrolment
01/09/2014

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre and Sophia Children's Hospital
Burg. 's-Jacobdsplein 51
Rotterdam
Netherlands

Sponsor information

Organisation
Erasmus Medical Center

Sponsor details
Burg. 's-Jacobdsplein 51
Rotterdam
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3013 CA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Not defined

Funder Name
NutsOhra Fund (Fonds NutsOhra) (Netherlands)

Funder Name
Coolsingel Foundation (Stichting Coolsingel((Netherlands)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository