

Diagnose the red baby

Submission date 13/05/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/06/2015	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 Maastricht 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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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) according to all possible diagnoses in erythrodermic newborns.

Intervention Type

Mixed

Primary outcome(s)

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.).

Key secondary outcome(s)

Morbidity and mortality

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes