

# Diagnose the red baby

<b>Submission date</b> 13/05/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/06/2015	<b>Condition category</b> 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

**Study website**  
[www.huidhuis.nl/afdeling/neonatale-erythrodermie](http://www.huidhuis.nl/afdeling/neonatale-erythrodermie)

## Contact information

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Scientific

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Scientific

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3013 CA

## 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) according 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  
Netherlands  
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