# Table salt for the treatment of umbilical granuloma

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The aim of this observational study is to evaluate the treatment of umbilical granulomas with

table salt.

**Ethical review** Approved WMO **Status** Recruiting

**Health condition type** Cutaneous neoplasms benign

**Study type** Interventional

## **Summary**

#### ID

NL-OMON51519

Source

ToetsingOnline

**Brief title** 

table salt for umbilical granuloma

#### **Condition**

Cutaneous neoplasms benign

#### **Synonym**

umbilical granuloma

#### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** GGD Fryslan

Source(s) of monetary or material Support: niet van toepassing

#### Intervention

**Keyword:** neonate, table salt, umbilical granuloma

#### **Outcome measures**

#### **Primary outcome**

The number of umbilical granulomas which has disappeared one week, two weeks and a month after treatment, as a proportion of all umbilical granulomas treated..

#### **Secondary outcome**

adverse effects

satisfaction of parents/caregivers and health care professionals.

# **Study description**

#### **Background summary**

In some newborns, after the umbilical cord has dried up, an umbilical granuloma develops. An inflammation can develop at the site of this umbilical granuloma. Umbilical granulomas are therefore treated by using silvernitrate. This treatment is usually successful, but carries the risk that silver nitrate can get on healthy skin. This causes blisters and is painful. The treatment of navel granuloma with table salt is a common treatment in the United Kingdom and other countries.

#### Study objective

The aim of this observational study is to evaluate the treatment of umbilical granulomas with table salt.

#### Study design

This is an observational study.

#### Intervention

application of table salt on the granuloma of the umbilicus.

#### Study burden and risks

The burden for the child is that table salt will be applied on the granuloma for a number of days. This is painless, even with a spill. The burden on parents is that they have to apply the salt three times a day for a number of days. We also ask them to complete a questionnaire. Finally, we ask them to take a picture. In our opinion, this is a relatively small burden.

### **Contacts**

#### **Public**

**GGD** Fryslan

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Scientific

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## **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Babies and toddlers (28 days-23 months)

#### Inclusion criteria

children of at least 25 days of age without other significant problems

#### **Exclusion criteria**

no informed consent doubt about understanding aim of study, such as not fluent in Dutch any significant medical or surgical disease of the child

## Study design

## **Design**

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

#### Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 23-03-2023

Enrollment: 30

Type: Actual

## **Ethics review**

Approved WMO

Date: 29-12-2022

Application type: First submission

Review commission: RTPO, Regionale Toetsingscie Patientgebonden Onderzoek

(Leeuwarden)

## **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

# Other (possibly less up-to-date) registrations in this register

No registrations found.

# In other registers

Register ID

CCMO NL81777.099.22