Table salt for the treatment of umbilical granuloma

Published: 29-12-2022
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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

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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