The First Bratelle study, a prospective, single-arm, pilot study to confirm the efficacy of the Bratelle breast-pads, that has been experienced by a small group of individual patients, in a larger group and in a controlled setting.

Published: 20-01-2020
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Primary, improvement of the quality of life.Secondary, reduction of pain and a decrease of the number of treatments by a breast oedema therapist.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries by physical agents
Study type	Interventional

Summary

ID

NL-OMON48727

Source
ToetsingOnline

Brief title
FILLE study

Condition

- Injuries by physical agents
- Skin and subcutaneous tissue disorders NEC
- Lymphatic vessel disorders

Synonym
'breast edema', 'fluid in a breast'

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Didert B.V.,Financiering door de sponsor en vanuit bedrijven.,Lacidem,Lohmann & Rauscher

Intervention

Keyword: Bratelle, Breast, Cancer, Oedema

Outcome measures

Primary outcome

Improvement of the Quality of Life score assessed using the EORTC QLQ-CR30 en

QLQ-BR23 questionnaires.

Secondary outcome

Improvement of the Pain NRS.

Reduction of the number of necessary treatments by a breast oedema therapist

Study description

Background summary

Use of the Bratelle breast-pads by a few, individual patients has resulted in an improvement of symptoms resulting from breast oedema. The Fille study aims to confirm this anecdotal efficacy in a larger group of patients, 30 in total, in a controlled setting.

Study objective

Primary, improvement of the quality of life.
Secondary, reduction of pain and a decrease of the number of treatments by a breast oedema therapist.

Study design

Prospective, feasibility study

Intervention

The Bratelle breast-pads are used whenever the patient is wearing a bra for a period of 3 months (study duration).

Study burden and risks

Participation in the Fille study is associated with a relative mild burden for a period of 3 months. The Bratelle breast-pads can be easily positioned in the bra and have a soft surface so that wearing the pads is not inconvenient or painful.
There are no specific risks associated with the use of the Bratelle breast-pads.

Contacts

Public
Meander Medisch Centrum

Maatweg 3 3
Amersfoort 3813 TZ
NL
Scientific
Meander Medisch Centrum

Maatweg 3 3
Amersfoort 3813 TZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female with breast edema, existing for more than 1 year, as a result of treatment for breast cancer with breast conserving surgery and radiotherapy.

Exclusion criteria

Ongoing radiotherapy, open skin lesions and not able to wear the Bratelle breast-pads, previous treatment with the Bratelle.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Komprex II
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-01-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL64992.100.19