Interventional ductoscopy in patients with (premalignant) intraductal lesion(s)

Published: 27-01-2022
Last updated: 05-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54094

Source
ToetsingOnline

Brief title
EVAPORATE

Condition

- Breast therapeutic procedures

Synonym
nipple fluid, Pathological nipple discharge

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF,Abegaill B.V.

Intervention

Keyword: Ductoscopy, Minimaly invasive surgery, Pathological nipple discharge

Outcome measures

Primary outcome

Primary endpoints are to determine the number of intraductal lesions diagnosed

and treated by using intraductal biopsy and laser ablation.

Secondary outcome

To analyze treatment success of interventional ductoscopy and quality of life

after ductoscopy in patients with PND. Also, in patients who undergo surgery,

to determine the accuracy of findings of biopsy and laser ablation during

ductoscopy

Study description

Background summary

Ductoscopy is a minimally invasive micro-endoscopic approach for direct visualization of intraductal lesions of the breast. One of the limitations of ductoscopy is that the current biopsy tool is not sufficiently accurate to obtain biopsy for pathology to confirm what is seen during ductoscopy. This could lead to overtreatment when a visual diagnosis is uncertain. Therefore, new intraductal biopsy tools were developed to perform this biopsy. Additionally, it would be interesting to perform an intraductal laser ablation for lesions that are unable to extract with the biopsy devices. In this study, we will analyze two new implementations to enhance the interventional ductoscopy technique: new intraductal biopsy tools and intraductal laser ablation in patients with (premalignant) intraductal lesions. The main aims of the present study are to improve diagnostic accuracy and therapeutic efficacy of interventional ductoscopy in patients with PND and to explore the feasibility of the new implementations in diagnosing and removing intraductal precursor lesions. We hypothesize that the newly developed biopsy tools and laser ablation will enhance the technique to perform a biopsy and remove (premalignant) intraductal lesions more specifically.

Study objective

The primary objective is to assess the feasibility of intraductal biopsy and intraductal laser ablation in patients with intraductal lesions. Secondary objectives are: treatment success of interventional ductoscopy (biopsy and laser ablation) in treating pathological nipple discharge (PND), to analyze the effectivity of intraductal biopsy and laser ablation in completely removal of the intraductal lesion(s).

Study design

A prospective, single-center, diagnostic feasibility study.

Intervention

Patients with intraductal lesion(s) will undergo an intraductal biopsy with newly designed biopsy tools and laser ablation.

Study burden and risks

The study population will not have any diasadvantage of participation. Patients who are already eligible for ductoscopy will not have additional examinations and/or visits. The ductoscopy procedure will take 10 minutes more than usual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Women >=18 age
• Patients with unilateral pathological nipple discharge
• No radiological suspicion for malignancy
• Referred to the UMC Utrecht for ductoscopy

Exclusion criteria

• Pregnancy
• History of breast surgery at the affected breast
• History of radiotherapy of the breast or thorax
• Nipple retraction making ductoscopy technically impossible
• Not being able to sign an informed consent

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2022
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Biopsy tools
Registration:	No

Ethics review

Approved WMO Date:	27-01-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-07-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL77552.041.21