

Detection of early premalignant breast lesions by autofluorescence ductoscopy

Published: 10-04-2014

Last updated: 24-04-2024

Is ductoscopy with white light and autofluorescent light a useful method for diagnosing precancerous breast lesions?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON40131

Source

ToetsingOnline

Brief title

Autofluorescence ductoscopy

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym

breast cancer; breast carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Pink Ribbon

Intervention

Keyword: autofluorescence, breast cancer, ductoscopy, endoscopy

Outcome measures

Primary outcome

With this study the (technical) feasibility of autofluorescence ductoscopy will be studied. The number and characteristics of intraductal lesions found with the two different types of ductoscopy (white-light vs. autofluorescence) will be compared. The number and visual characteristics of lesions found (and marked) by ductoscopy will be compared to the number and characteristics of lesions found by pathological analysis of the mastectomy specimens.

Secondary outcome

To investigate the correlation between the projected characteristics of a precursor lesion in white and autofluorescent light and its histological characteristics.

*

Study description

Background summary

Breast cancer remains the leading cause of mortality among women in the Western world. For example, in the Netherlands, breast cancer is the most commonly diagnosed neoplasm in women. Although survival has been improved, eventually 25% of the breast cancer patients will die of their disease. Best approach in minimizing morbidity and mortality related to breast cancer, is by preventing the development of breast cancer.

In women with the highest breast cancer risk, e.g. carriers of a BRCA mutation, in order to prevent breast cancer surgical removing both breasts reduces the incidence of breast cancer and improves survival, but is an invasive surgical treatment and some of these women would have never developed breast cancer and therefor receive overtreatment. However, conventional imaging misses about 40% of the early staged breast cancer lesions. More sensitive screening and non-invasive treatment methods of early precursor breast lesions would therefore have a lot of benefits.

Ductoscopy is a minimally invasive micro-endoscopic approach for direct visualization of intraductal lesions of the breast. Autofluorescence is a noninvasive imaging technique added to ductoscopy that might help to identify intraductal precursor lesions of breast cancer under direct vision.

Study objective

Is ductoscopy with white light and autofluorescent light a useful method for diagnosing precancerous breast lesions?

Study design

This is a prospective invasive observational phase II cohort study.

Study burden and risks

The study population will not have any benefit of participation. Since all procedures will be performed under general anesthesia in the operating room there will be no physical discomfort. Ductoscopy is a minimally invasive procedure, known to have only minor complications, being nipple pain and duct perforation. Since all patients are undergoing mastectomy they will not suffer from any of the known complications of the ductoscopy procedure. Pathological analysis of the breast will not be interfered since we will only use intraductal saline infusion to facilitate the ductoscopy. There will be no risk of spread of tumor cells in the breast cancer group, since it is a non-invasive method and all patients will receive a mastectomy directly afterwards. The duration of anesthesia will be prolonged half an hour by the ductoscopy. There will be no extra tests, visits, questionnaires or diaries.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX

NL

Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Women ≥ 18 age
- Indication for mastectomy by recently pathologically proven malignancy OR choosing preventive mastectomy because of highly increased risk of breast cancer development.

Exclusion criteria

- Pregnant women
- Under 18 years of age
- Former radiotherapy of thorax or breast (on the site of the operated breast)
- Former surgery of the nipple or areola (on the site of the operated breast)

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 14-10-2014
Enrollment: 30
Type: Actual

Medical products/devices used

Generic name: Autofluorescence ductoscopy
Registration: Yes - CE outside intended use

Ethics review

Approved WMO
Date: 10-04-2014
Application type: First submission
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO
Date: 10-12-2014
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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

CCMO

ID

NL43991.041.13