Optical vulvar biopsy by optical coherence tomography (OCT)

Published: 18-05-2010
Last updated: 10-08-2024

To determine the diagnostic value of OCT in patients with (suspicion of) vulvar intraepithelial neoplasia and in patients with vulvar cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON34664

Source
ToetsingOnline

Brief title
Optical vulvar biopsy by OCT

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
premalignant vulvar cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: NKI/AVL

Intervention

Keyword: OCT, vulva

Outcome measures

Primary outcome

To determine the sensitivity, specificity, positive predictive and negative predictive value of OCT for the presence of VIN and invasive cancer in patients with suspicion of VIN or vulvar cancer.

Secondary outcome

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Study description

Background summary

Optical coherence tomography (OCT) is an emerging biomedical optical imaging technique that performs high resolution, cross sectional tomographic imaging generating pictures that resemble histopathological examination1. By this high resolution OCT functions as a type of *optical biopsy* providing cross sectional images of tissues in analogy to histopathology but without removal or staining tissue. Presently, OCT is widely used in ophthalmology where it has become a key diagnostic tool in the areas of retinal disease and glaucoma. Vulvar intraepithelial neoplasia (VIN) is a premalignant disease, caused by HPV16 with often severe and long-lasting complaint. The progression rate to cancer is about 8% without treatment. The presence of an occult carcinoma at diagnosis is 3.2%, although in several studies it is as high as 20.5%. The incidence of VIN is increasing dramatically the last three decades. Standard management of the patients consisted until recently of taking multiple *mapping* biopsies to exclude invasion followed by conservative surgical excisions and/or laser vaporization, however every attempt is made to avoid vulvar mutilation1. In 2008 the application of imiquimod, an local immune modulating agent, became the standard treatment, giving a complete remission rate of VIN of 35% and a partial remission rate of 46%. With this conservative management, however, there is an urgent need for an effective diagnostic tool to foresee occult invasion. Optical coherence tomography (OCT) might be such a test. OCT has been shown to be useful in the qualitative and quantitative assessment of normal skin. In the cervix uteri it improves the sensitivity and specificity of coplopscopy for high grade cervical intraepithelial neoplasia (CIN) to 76% resp 61%. It was never evaluated in vulvar skin or VIN.

Study objective

To determine the diagnostic value of OCT in patients with (suspicion of) vulvar intraepithelial neoplasia and in patients with vulvar cancer.

Study design

It is a prospective observational study. In total 100 measurements will be made in 25 patients. The OCT images will be correlated to the histopathological results. In patients with (suspicion of) vulvar intraepithelial neoplasia, in whom during the diagnostisc work-up or during follow up a diagnostic biopsy has to be taken, the vulvar skin at the place of the biopsy will be scanned with the OCT device. In patients with vulvar cancer the vulvar skin will be scanned with the OCT device within the resection margins . A maximum of 5 biopsies will be taken.

Study burden and risks

OCT is harmless, it uses light that enters the skin several mm. Presently, OCT is widely used in ophthalmology where it has become a key diagnostic tool in the areas of retinal disease and glaucoma. Patient's gynaecologic exam is extended with 15 minutes or the operation is extended with 15 minutes.

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

Patients with suspicion of vulvar intraepithelial neoplasia
Patients with vulvar cancer

Exclusion criteria

Patients without suspicion of vulvar intraepithelial neoplasia
Patients without vulvar cancer

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2010
Application type:	First submission
Review commission:	PTC Nederlands Kanker Instituut (Amsterdam)

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	NL31197.031.10