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Colposcopy and preterm birth study

Submission date	Recruitment status	[_] Prospectively registered
30/10/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/12/2017	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/09/2022	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Human papillomavirus (HPV) causes infections of the cervix in women, which can lead to cancer precursor lesions and, if untreated, cervical cancer. There are approximately over 200 types of HPV known to date, some presenting a higher risk for developing precancerous disease. HPV infections are very common as nearly all sexually active individuals get infected during their lifetime and many of these infections are cleared without treatment. HPV related changes in the cervix can be detected by Pap smears (a test that collects cells from the cervix). After an abnormal Pap smear result the cervix can be examined with colposcopy and punch biopsies can be taken to determine the best course of action. If a moderate or severe lesion is diagnosed in the cervix the most common treatment is LLETZ (large loop excision of the transformation zone). LLETZ has a good cure rate for cancer precursors, but it has been associated with increased risk of preterm delivery in subsequent pregnancies. The exact reason underlying this is still unknown and even women with mild lesion that have regressed during active surveillance without any treatment have shown a slightly increased risk for preterm delivery. The aim of this study is to assess the risk for preterm delivery after colposcopy and/or cervical treatment as well as assess the prevalence, clearance and incidence of new HPV genotype infections within two years of recruitment. It also aims to assess the sensitivity and specificity of the colposcopic examination and the rates and risk factors for complications of colposcopy or treatments.

Who can participate?
Women aged 18 and older who are referred to have a colposcopy.

What does the study involve?
Participants receive a colposcopy as done to the standard level of care. At the start of the study, participants fill out a detailed questionnaire about their general health, sexual habits and history. During colposcopy visits up to two years from recruitment an extra cervical brush sample is taken. Data is taken from participant's hospital records and national health registries until death or if they move out of the country.

What are the possible benefits and risks of participating?
Participants may benefit from the possibility to get extra information on the HPV genotype(s) behind the condition being treated/followed-up, in usual clinical practice we commonly only test for the presence of high-risk HPV viruses. There is no risk in participating in the trial as treatment and follow-up is done according to current treatment guidelines.

Where is the study run from?
Helsinki University Hospital, Womens' Clinic (UK)

When is the study starting and how long is it expected to run for?
January 2014 to December 2050

Who is funding the study?
Helsinki University Central Hospital (Finland)

Who is the main contact?
Professor Pekka Nieminen
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Helsinki colposcopy and preterm birth cohort study

Acronym
HELICOPTER

Study objectives
Treatment of the cervix for cancer precursors has been shown to increase the risk for preterm delivery in retrospective data.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki University Hospital District, 24/04/2013, ref: 130/13/03/03/2013

Study design
Observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Gynaecological HPV related diseases where patients have been referred to colposcopy.

Interventions
Participants in this trial are treated according to current treatment guidelines and followed at the colposcopy clinic accordingly. At enrolment participants fill in a detailed questionnaire on their general health, sexual habits and history. At each follow-up visit until two years after enrolment an extra cervical sample is obtained. Data on participants is extracted from hospital records and national health registries. The first observation period for the participants is up to two years. Hospital and national records may be re-reviewed until the participants death or moving out of the country.

Intervention Type
Other

Primary outcome(s)
Incidence of preterm birth after colposcopy and/or cervical treatment is measured using the information in hospital records and national health registries at five, seven and ten years after enrollment.

Key secondary outcome(s))
1. Prevalence, clearance, and incidence of new HPV infections is measured with the extra cervical brush samples (HPV genotyping) obtained at any visit at the colposcopy clinic up to two years after enrolment
2. Sensitivity and specificity of colposcopic evaluation is measured using data from hospital records up to two years after enrolment
3. Rate of complications of colposcopy and treatment and risk factors are measured using using data from hospital records up to two years after enrolment

Completion date
31/12/2050

Eligibility

Key inclusion criteria
1. Any woman 18 years of age or older
2. Referred to colposcopy at Helsinki University Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
1279

Key exclusion criteria
Under the age of 18

Date of first enrolment
13/01/2014

Date of final enrolment
13/05/2016

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital, Womens' Clinic
Haartmaninkatu 2
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Sponsor information

Organisation
University of Helsinki and Helsinki University Hospital

ROR

https://ror.org/02e8hzf44

Funder(s)

Funder type
Government

Funder Name
Helsingin ja Uudenmaan Sairaanhoitopiiri

Alternative Name(s)
Helsinki University Central Hospital, HUS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Finland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	population-based results for the association between loop electrosurgical excision and subsequent preterm delivery	01/02/2018	11/04/2019	Yes	No
Results article	HPV type distribution results	01/08/2019	11/06/2019	Yes	No
Results article		21/09/2022	29/09/2022	Yes	No