ISRCTN10836802 https://doi.org/10.1186/ISRCTN10836802

Risk of cervical cancer among women who took an HPV test in 1990-1992, a 30-year follow-up study

Submission date
14/12/2020

Recruitment status
No longer recruiting

Registration date
23/12/2020

Overall study status
Completed

Last Edited
24/06/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Almost all cases of cervical cancer are caused by Human Papilloma Virus (HPV). HPV is a very common virus that can be passed on through any type of sexual contact with a man or a woman. There are more than 100 types of HPV, many of which are harmless. But some types can cause abnormal changes to the cells of the cervix, which can eventually lead to cervical cancer. Cancer of the cervix ranks fourth of cancer types for both incidence and mortality among women worldwide. Long-term follow-up of patients with positive tests for HPV is insufficiently studied. The study objective was to compare HPV status at baseline with the risk of CIN3+ in the follow-up period of 30 years.

Who can participate?
All women referred to the HPV outpatient clinic at the University Hospital of Northern Norway (UNN) in 1990-1992, with an HPV test at baseline, were included in this retrospective cohort.

What does the study involve?
The study involves HPV-results from 1990-1992, using a two-step nonradioactive DNA hybridization method (ONCOR). In addition, a polymerase chain reaction (PCR) method using papilloma consensus primers was performed. Biopsy-verified CIN3+ was detected during follow up.

What are the possible benefits and risk of participating?
Participants may benefit from the possible detection of HPV which makes it possible to follow-up and treat precancer before the development of cervical cancer. No additional risks are anticipated.

Where is the study run from?
The University Hospital of Northern Norway.

When is the study starting and how long is it expected to run for?
October 2018 to December 2020. HPV testing was done in August 1990 to December 1992.

Who is funding the study?
This research was supported by the University Hospital of North Norway (http://www.unn.no/). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Who is the main contact?
Dr Sveinung Wergeland Sorbye, sveinung.sorbye@unn.no

Contact information

Type(s)
Scientific

Contact name
Dr Sveinung Wergeland Sorbye

ORCID ID
https://orcid.org/0000-0002-8250-3992

Contact details
Department of Clinical Pathology
University Hospital of North Norway
Box 46
Tromso
Norway
9038
+47 77627223
sveinung.sorbye@unn.no

Additional identifiers

Protocol serial number
2011/2397/REK Nord

Study information

Scientific Title
Long-term follow-up of patients with positive tests for HPV in 1990-1992, comparing HPV status at baseline with the risk of cervical intraepithelial neoplasia grade 3 or higher (CIN3+) in the follow-up period of 30 years

Acronym
LTFU 30

Study objectives
Women with positive HR-HPV test have a higher long-term risk of CIN3+ compared to HR-HPV negative women.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 06/12/2011, The Regional Committee for Medical and Health Research Ethics, North Norway (REK North, iT The Arctic University of Norway, Box 6050 Langnes, 9037 Tromso, Norway; +47 776 46 140; rek-nord@fagmed.uit.no), ref: 2011/2397/REK Nord

Primary study design
Observational

Study design
Retrospective cohort comparing HR-HPV positive and HR-HPV negative regarding the risk of CIN3+ during 30 years of follow up

Study type(s)
Screening

Health condition(s) or problem(s) studied
Investigating the risk of CIN3+ in patients with an HPV test at UNN in 1990-1992

Interventions
Observational trial: an exposed cohort consisting of women with a positive HR-HPV test (N=223) was compared to a control cohort consisting of women with a negative HR-HPV test (N=419). During the period of follow-up, we detected all incidents of CIN3+ within our study population, comparing HPV status at baseline with the incidence of CIN3+.

Intervention Type
Other

Primary outcome(s)
Detection of cervical cancer during follow up period, measured by biopsy and recorded in patient records

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2020

Eligibility

Key inclusion criteria
All women referred to the HPV outpatient clinic at the University Hospital of Northern Norway (UNN) in 1990-1992, with an HPV test at baseline

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
642

Key exclusion criteria
History of medical or surgical treatment for cervical cancer.

Date of first enrolment
18/08/1990

Date of final enrolment
31/12/1992

Locations

Countries of recruitment
Norway

Study participating centre
The University Hospital of Northern Norway (UNN)
Sykehusveien 38
Tromsø
Norway
9038

Sponsor information

Organisation
University Hospital of North Norway

ROR
https://ror.org/030v5kp38

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitetssykehuset Nord-Norge

Alternative Name(s)
University Hospital of North Norway

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/06/2021	24/06/2021	Yes	No