

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	<input type="checkbox"/> Prospectively registered
Registration date 23/12/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/06/2021	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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 Tromsø, Norway; +47 776 46 140; rek-nord@fagmed.uit.no), ref: 2011/2397/REK Nord

Study design

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

Primary study design

Observational

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes