

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

<b>Submission date</b> 14/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/06/2021	<b>Condition category</b> 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?

Dr Sveinung Wergeland Sorbye, [sveinung.sorbye@unn.no](mailto:sveinung.sorbye@unn.no)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

No participant information sheet available (retrospective study)

**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 measure**

Detection of cervical cancer during follow up period, measured by biopsy and recorded in patient records

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

10/10/2018

## **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

## **Age group**

Adult

## **Sex**

Female

## **Target number of participants**

642

## **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

### Sponsor details

Sykehusveien 38

Tromsø

Norway

9019

+47 77626000

postmottak@helse-nord.no

### Sponsor type

Hospital/treatment centre

### Website

[http://www.unn.no/?lang=en\\_US](http://www.unn.no/?lang=en_US)

### 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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

01/02/2021

## 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?
<a href="#">Results article</a>		22/06/2021	24/06/2021	Yes	No