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**
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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 Tromso, 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

**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? |
|---|---|---|---|---|---|
| Results article | | 22/06/2021 | 24/06/2021 | Yes | No |