A phase IIIb, open, multi-centre gynaecological extension study for the follow-up of a subset of HPV-015 study subjects

Published: 06-09-2010
Last updated: 04-05-2024

To provide clinical management and, if required, treatment to subjects who at their concluding HPV-015 study visit displayed normal cervical cytology but tested positive for oncogenic HPV infection or who were pregnant at their concluding visit of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON38130

Source
ToetsingOnline

Brief title
Gynaecological follow-up of a subset of HPV-015 study subjects

Condition

- Viral infectious disorders
- Reproductive neoplasms female malignant and unspecified
- Cervix disorders (excl infections and inflammations)

Synonym
Cervical cancer, Human Papillomavirus infection

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Cervical cancer, Gynaecological follow-up, HPV infection

Outcome measures

Primary outcome

- Occurrence of positive oncogenic HPV DNA results in cervical samples by HPV

DNA testing (Hybrid Capture® 2 test [HC2])

- Occurrence of cervical cytological abnormalities in cervical samples by

ThinPrep® PapTest

- Occurrence of referral to colposcopy

- Occurrence of referral to treatment

Secondary outcome

Not applicable

Study description

Background summary

Study subjects enrolled in the control arm of the HPV-015 study may have been infected with the HPV types included in the vaccine during the study. All subjects may have been exposed to other high-risk HPV types. The current study will provide annual oncogenic HPV DNA testing and cervical cytology examination for a subset of HPV-015 subjects who at their concluding HPV-015 study visit: displayed normal cervical cytology but tested positive for oncogenic HPV infection or were pregnant so that no cervical sample could be collected.

Study objective

To provide clinical management and, if required, treatment to subjects who at

their concluding HPV-015 study visit displayed normal cervical cytology but tested positive for oncogenic HPV infection or who were pregnant at their concluding visit of the HPV-015 study so that no cervical sample could be collected.

Study design

A phase IIIb, open, multi-centre gynaecological extension study for the follow-up of a subset of HPV-015 study subjects in Asian-Pacific, Europe, Latin-America and North-America with approximately 1500 study subjects. Annual gynaecological follow-up, oncogenic HPV DNA testing and cervical cytology examination for a subset of HPV-015 subjects. Visits in month 12, 24, 36 and 48. Subjects will enter the study approximately one year after their HPV-015 concluding study visit: Visit 9, Visit 11 or at the last study visit in HPV-015 planned under protocol amendment 4.

Intervention

In the HPV-015 (104820) study the following groups were randomised:
One group randomised to HPV (HPV-16/18 L1/AS04) vaccination (0,5ml intramuscular) in month 0, 1 en 6
One group randomised to conrol (Al(OH)3) vaccination (0,5ml intramuscular) in month 0, 1 en 6

Study burden and risks

Study subjects will undergo annual gynaecological examination, collection of cervical cytology samples and if applicable, colposcopy. These study procedures are according to local medical practice and are performed by medical qualified personnel. However, the procedures may cause adverse effects or inconvenience to study subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- A subjects previously enrolled in the HPV-015 study
- A subject with normal cervical cytology but positive test result for oncogenic HPV infection at concluding HPV-015 study visit
- A subject that was pregnant so that no cervical sample could be collected at concluding HPV-015 study visit

Exclusion criteria

- A subject with normal cervical cytology and negative test result for oncogenic HPV infection at concluding HPV-015 study visit
- A subject with a cervical lesion or with a cervical lesion that required treatment at concluding HPV-015 study visit
- A subject for whom the cervical cytology results were unavailable for reasons other than pregnancy at concluding HPV-015 study visit

Study design

Design

Study phase: 3

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2011
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cervarix

Ethics review

Approved WMO

Date:	06-09-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-09-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-08-2011
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	26-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-017282-35-NL
CCMO	NL33307.098.10