A Randomized, Observer-blind, First-in-Human Phase 1/2a Study to Evaluate the Safety, Reactogenicity and Immunogenicity of Three Different Doses of VAC52416 (ExPEC10V) in Adults Aged 60 to 85 Years in Stable Health

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Ethical review	Approved WMO
Status	Completed
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON52538

Source
ToetsingOnline

Brief title
VAC52416BAC1001

Condition

- Bacterial infectious disorders

Synonym
E. coli infection, invasive extraintestinal pathogenic E. coli (ExPEC) disease

Research involving

Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen-Cilag BV

Intervention

Keyword: E. coli, Escherichia coli, ExPEC10V, Urinary tract infection, Vaccine

Outcome measures

Primary outcome

Solicited local and systemic AEs collected for 14 days post-vaccination

(Solicited (local and systemic) AEs are precisely defined events that participants are specifically asked about and which are noted by participants through the participant ediary)

Unsolicited AEs collected from the administration of the study vaccine until 29 days post-vaccination

(Unsolicited AEs are all AEs for which the participant is not specifically questioned in the participantediary).

SAEs collected from the administration of the study vaccineuntil Day 181

Antibody titers for ExPEC10V, as determined by multiplex ECL-based immunoassayand MOPA on Day 30

Secondary outcome

Antibody titers for ExPEC10V, as determined by multiplex ECL-based

immunoassayand MOPA on Day30

Antibody titers for ExPEC10V, as determined by multiplex ECL-based immunoassay

on Days15 and 181 and MOPA on Day 181

SAEs related to the study vaccine or study procedures collected from Day 182

until the end of the study

Antibody titers for ExPEC10V, as determined by multiplex ECL-based immunoassay

and MOPA at Year 1 (Day 366)

Study description

Background summary

ExPEC10V is a 10-valent vaccine candidate in development for the prevention of invasive extraintestinal pathogenic Escherichia coli (ExPEC) disease (IED) in adults 60 years of age and older.

ExPEC are a leading and rising cause of bacteremia and bloodstream infections worldwide, and comprise17% to 37% of clinically significant blood isolates.

The worldwide emergence of multidrug resistance (ie,resistance to three or more antibiotic classes) among ExPEC strains represents a major challenge for the prevention and management of ExPEC infections.

Although IED affects all age categories, adults aged 60 years or older have an increased risk of developing IED.
At present, there is no vaccine available to prevent IED. ExPEC10V is being developed to prevent IED in adults 60 years of age and older.

Study objective

The sites of the Netherlands will only participate in cohort 2.
Primary objectives - cohort 2:
- To evaluate the safety and reactogenicity of the selected dose of ExPEC10V in participants >=60 years of age with a history of UTI in the past 5 years
- To evaluate the immunogenicity of the selected dose of ExPEC10V on Day 30 in participants >=60 years of age with a history of UTI in the past 5 years

Secondary objectives - cohort 2:

- To evaluate the correlation between multiplex ECL-based immunoassay (total antibody) and MOPA (functional antibody) serum titers on Day 30
- To evaluate the immunogenicity of the selected dose of ExPEC10V on Days 15 and 181
- To evaluate, in the LTFU period, the safety and immunogenicity of the selected dose of ExPEC10V

Study design

This is a phase 1 / 2a study to investigate the safety, reactogenicity and immunogenicity of 3 different doses of the vaccine EXPEC10V in adults 60 - 85 years of age in stable health.
Cohort 1 of this study was conducted in the United States. For Cohort 1, the primary objective of the study was to evaluate the safety and reactogenicity of different doses of ExPEC10V.
Cohort 2 will be conducted in the United States and several European countries. For Cohort 2, the primary objective of the study is to evaluate the safety and reactogenicity of the selected dose of ExPEC10V from Cohort 1.

Intervention

Cohort 2:
- 1 administration of the study vaccine EXPEC10V (selected dose from cohort 1) on day 1 of the study.

Study burden and risks

The subjects will not derive any personal health benefits from participating in this study, but the results obtained from this study may be important for the development of vaccines and treatments that may be beneficial to the health of others. For example, their participation can help prevent other people from getting a urinary tract infection in the future.

Disadvantages of participating in the study may include:
- possible side effects of the study vaccine.
- possible inconveniences of the measurements in the study (e.g. blood tests, maximum 7 times).

The safety profile of ExPEC10V has not yet been established. However, clinical data are available for the ExPEC4V vaccine without new safety concerns. The nature and production processes of ExPEC4V and ExPEC10V are similar. Therefore, the safety profile of ExPEC10V is expected to be similar to that of ExPEC4V. In addition, the EXPEC10V vaccine was administered to more than 400 participants in the previous cohort 1 of this study.

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

- Must have a body mass index (BMI) of >18.5 to<40kg/m2;

- Before randomization, a woman must be:
a). postmenopausal - A postmenopausal state is defined as no menses for 12 months without an alternative medical cause; or
b). not intending to conceive by any methods;

- Must be healthy or medically stable

- Must sign an ICF indicating that he or she understands the purpose of, and procedures required for,the study and is willing to participate in the study;

- Willing and able to adhere to the lifestyle restrictions specified in this protocol

- Agrees not to donate blood until 12 weeks after receiving the study vaccine

Exclusion criteria

- Acute illness (this does not include minor illnesses such as diarrhea or mild upper respiratory tract infection) or temperature >=38.0ºC (100.4°F) within 24 hours prior to the administration of study vaccine, or, applicable for Cohort 2 only, an ongoing or suspected symptomatic UTI; enrollment at a later date is permitted (provided the screening window of 28days is respected);

- History of malignancy within 5 years before screening (exceptions are squamous and basal cell carcinomas of the skin and carcinoma in situ of the cervix, or malignancy, which is considered cured with minimal risk of recurrence);

- Known allergies, hypersensitivity, or intolerance to ExPEC10V or its excipients (refer to Investigator's Brochure);

- Contraindication to IM injections and blood draws eg, bleeding disorders;

- Abnormal function of the immune system

- Has had major psychiatric illness and/or drug substance or alcohol abuse in the past 12months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-10-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-09-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-09-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-01-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-05-2021

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-01-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-01-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2020-000657-27-NL
ClinicalTrials.gov	NCT03819049
CCMO	NL74093.000.20