Exploratory study into age-related immunological differences related to immunogenicity in influenza vaccination and herpes zoster vaccination

Published: 05-01-2021
Last updated: 27-04-2024

The general objective of this study is to identify immune senescence related pathways leading to different immunogenicity after administration of unadjuvanted influenza or AS01 adjuvanted herpes zoster vaccines.

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

Summary

ID

NL-OMON50860

Source
ToetsingOnline

Brief title
INFLUENZA-SHINGRIX

Condition

- Viral infectious disorders

Synonym
herpes zoster, Influenza

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ERC grant en GSK,GlaxoSmithKline

Intervention

Keyword: Adjuvanted herpes zoster vaccine, Immune senescence, Quadrivalent inactivated influenza vaccine, Trained immunity

Outcome measures

Primary outcome

Functional assessment of vaccine response (including but not limited to

antibody responses, cellular mediated immune responses, cross-omics, cytokine

production)

Secondary outcome

Safety data (solicited AEs, unsolicited AEs, SAEs, MAAEs, AESIs, AEs leading to

withdrawal from the study and unintentional exposure during

pregnancy)

Study description

Background summary

Vaccines are used to prevent infectious diseases worldwide. Unfortunately, many vaccines, like the flu vaccine, are less effective in the elderly. In this study we would like to assess the differences in immune response between young and older adults after vaccination with two different vaccines. One of the vaccines is known to work well in the elderly, the other is less effective. Exploring the underlying mechanisms can be used in future development of vaccines.

Study objective

The general objective of this study is to identify immune senescence related pathways leading to different immunogenicity after administration of unadjuvanted influenza or AS01 adjuvanted herpes zoster vaccines.

Study design

Open label, randomised and partially placebo-controlled study

Intervention

There are several interventions:
The older adults will receive either the influenza vaccine or the herpes zoster vaccine
Young adults will receive either the influenza vaccine, the herpes zoster vaccine or a placebo

Study burden and risks

Based on previous trials and experience in the use of these vaccines in the national vaccination programmes the risks of vaccination besides temporary local discomfort are negligible. The largest burden for participants is the frequency of blood collection, which is 8 visits for the herpes zoster vaccine group, and 5 for the influenza and 3 or 4 for the placebo groups. Altogether the time it takes for the participant is approximately 2.5 hours.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Healthy
• Age between 18-35 years old OR age >=65 years old
• Written informed consent

Exclusion criteria

• Known allergy to (components of) the influenza or herpes zoster vaccine
• Immunocompromised subjects
• Previous herpes zoster vaccination in the last year
• Receipt of any vaccination 4 weeks prior to the start of the study or plans to receive any other vaccination until 2 months after inclusion
• Chronic use of systemic drugs other than oral contraceptives
• Use of NSAIDS less than 4 weeks prior to the start of the study
• Acute or active illness within two weeks prior to the start of the study
• Pregnant, breastfeeding or planning to become pregnant during the study period

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2021
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Fluarix Tetra Northern Hemisphere 2021
Product type:	Medicine
Brand name:	Shingrix

Ethics review

Approved WMO Date:	05-01-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-10-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	02-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
Other	2020-005682-13
EudraCT	EUCTR2020-005682-13-NL
CCMO	NL76061.091.20

Study results

Date completed:	17-05-2023
Actual enrolment:	147