Timing and sequence of vaccination against COVID-19 and Influenza

Published: 29-04-2021
Last updated: 05-04-2024

Aim 1. To study the impact of different sequences of combined influenza and SARS-CoV-2 vaccinations on immunological responses and sideeffects.Aim 2. To understand the immunological mechanisms that mediate the potential interference between...

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

Summary

ID

NL-OMON51262

Source
ToetsingOnline

Brief title
TACTIC

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Corona, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: COVID-19, Influenza, SARS-CoV-2, Vaccine

Outcome measures

Primary outcome

Geometric mean titers of S-specific IgG in serum at 21 days after last vaccination

Secondary outcome

- Seroconversion of IgG to the SARS-CoV-2 spike protein at day 21 after the COVID-19 booster vaccines.

- Virus neutralization assays for the standard SARS-CoV-2 variant, as well as for the B1.1.7 and B1.351 variants

- IgA and IgG responses against RBD- and S- and N-protein in MLF and serum at baseline, 21 days after each vaccination

- IgG and IgA against influenza antigens in MLF and serum at baseline, 21 days after each vaccination

- Specific anti-SARS-CoV-2 T-cell responses against standard SARS-CoV-2 variant, as well as for the B1.1.7 and B1.351 variants

- Local reactions at injection site or systemic reactions after vaccination

- Serious adverse events and other adverse events.

Study description

Background summary

The COVID-19 pandemic is the greatest public health challenge that confronted humanity after World War II. COVID-19 has had a heavy impact on morbidity and

mortality, but also led to major economic and social disruptions in society. Vaccination is by far the most important strategy aimed to stop the pandemic and enable return to a normal situation, and it is crucial to ensure the effectiveness of COVID-19 vaccines. One factor that could influence effectiveness of vaccines is vaccine interference: as COVID-19 and influenza vaccines will probably be administered together at the end of the year, especially in risk groups for whom protection against these two diseases is very important, it is urgent to study the potential interference between these two vaccines and identify the best schedule that can ensure effectiveness.

Study objective

Aim 1. To study the impact of different sequences of combined influenza and SARS-CoV-2 vaccinations on immunological responses and side effects.
Aim 2. To understand the immunological mechanisms that mediate the potential interference between influenza and COVID-19 vaccines

Study design

Single-blind placebo controlled randomized trial
Participants (N=140) will be randomly assigned to one of the following groups (21day-intervals):

1 35 Influenza + placebo sample collection + Comirnaty booster sample collection
2 35 Comirnaty booster + placebo sample collection + Influenza sample collection
3 35 Influenza + Comirnaty booster sample collection + Placebo sample collection
4 (r) 35 Comirnaty booster + placebo sample collection + Placebo sample collection + Influenza*

Before every vaccination and 21 days after each vaccination (except for *), venous blood and mucosal lining fluid will be obtained.

Intervention

Vaccination against SARS-CoV-2 (by Pfizer or Janssen, depending on treatment group) & influenza

Study burden and risks

Venous blood sampling & mucosal lining fluid: minimal risk procedures (e.g. hematoma, itchy nose)

Side-effects vaccines: as stated in the respective product characteristics. Side effects are generally mild and self-limiting within days. The most important ones are pain at injection site (>90%), fatigue (>60%), headeach and myalgia (>50%).

Time-related burden for participants is minimal, visiting the study site 3 times taking 10-30 minutes per moment.

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

Age equal to or above 60 years
Received a COVID-19 vaccine 4-12 months prior to enrollment

Exclusion criteria

History of COVID-19 infection (confirmed by a microbiological test)
Vaccination against influenza <6months
Immunocompromised (either by co-morbidities or induced by medication)
Known allergy or history of anaphylaxis or other serious adverse reactions to vaccines
Acute illness < 2 weeks
Participation in another drug trial

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2021
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BNT162b2 COVID-19 vaccine
Product type:	Medicine
Brand name:	Influvac Tetra
Product type:	Medicine

Brand name:	Vaxigrip Tetra

Ethics review

Approved WMO Date:	29-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-08-2021
Application type:	First submission
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
EudraCT	EUCTR2021-002186-17-NL
CCMO	NL77590.091.21

Study results

Date completed:	26-11-2021
Actual enrolment:	160