Evaluating the effect of Agaricus bisporus powder intake on the vaccination response to an influenza vaccine

Published: 01-08-2023
Last updated: 05-10-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53177

Source
ToetsingOnline

Brief title
Agaricus bisporus and influenza vaccination response

Condition

- Other condition

Synonym
Decreased immune response

Health condition

verminderde immuunrespons

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: CNC Grondstoffen B.V.,Scelta Mycofriends B.V.,Scelta Mycofriends B.V. en CNC Grondstoffen B.V.

Intervention

Keyword: Agaricus bisporus, Immune system, Influenza vaccination, Mushroom

Outcome measures

Primary outcome

The main study endpoint is the vaccination response to an influenza vaccine.

Secondary outcome

Secondary endpoints include amongst others, hematological, inflammatory and

immunological parameters (e.g. hs-CRP, leukocyte differential count, cytokines)

and metabolic markers (e.g. blood lipid profiles, plasma glucose).

Study description

Background summary

There are numerous in vitro and animal studies that suggested that mushrooms beneficially influence the immune system. We have recently shown that a wild isolate of the edible Agaricus bisporus mushroom had a clear effect on parameters reflecting a better function of the immune system, both in vitro and in vivo in animals. The question now is whether this efficacy can also be translated to humans. In humans, measuring the antibody response is the golden standard to evaluate immune function. It has been shown previously that higher BMI and age are both negatively associated to vaccination responses. If mushrooms indeed have beneficial effect on the immune system, people with overweight or obesity and higher age might benefit from consuming mushrooms prior to receiving the influenza vaccination.

Study objective

The primary objective of this study is to demonstrate the effect of consuming daily 5 grams of Agaricus bisporus powder (10 capsules) on the vaccination response to an influenza vaccine in men and women aged 60 years or older during the influenza vaccination period 2023/2024.

Study design

A double-blind, randomized, placebo-controlled trial will be carried out. The intervention period lasts approximately 8 weeks. After this, around May first 2024, a questionnaire about influenza related symptoms will be filled out by the participants.

Intervention

The intervention group will receive 10 capsules daily containing Agaricus bisporus powder to reach a required dose of 5.0 gr Agaricus bisporus powder per day. The control group will receive placebo capsules containing maltodextrin of which the participants will also need to take 10 per day. Both capsules have the same shape and look identical. The capsules will be consumed divided over the day with the main meals.

Study burden and risks

: Subjects will be screened via telephone to determine eligibility. If a subject fulfills all criteria, a baseline visit is planned where the informed consent is obtained at the start. If the consent form is signed, a baseline blood sample will be taken and subjects will start consuming the active or placebo capsules until their influenza vaccination. This means that the time period between the start of consuming the Agaricus bisporus powder and the actual vaccination might slightly differ between participants, but the targeted period for consumption of the capsules is at least 4 weeks prior to the receiving the vaccination. Volunteers will be asked to visit the university for a second fasting blood sample the day before the vaccination. Following the influenza vaccination, study participants will continue to consume the capsules and will visit the university weekly for 4 additional weekly blood samples during the next 4 weeks. The 10 capsules will be consumed divided over the day as part of three main meals. There are no direct benefits for study subjects. The intervention and control capsules are considered to be safe. Some study subjects may report pain and/or a hematoma during or after the venipuncture. Subjects that do not fully adhere to the study protocol will be excluded from analyses in the per protocol analysis while be included in the intention-to-treat analysis. Time investment per participant will be approximately 4 hours in total, without considering any estimated travel time. The total blood sampling volume over the entire study period will be approximately 85 mL.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Aged 60 years or older during influenza season 2023/2024 (in line with RIVM guidelines)
BMI between 20 and 35 kg/m2
Willing to abstain from mushrooms other than the capsules containing a mushroom powder as provided by us during the study period.
Willing to keep the intake of fish oil, Zinc, Selenium and (vitamin) supplements constant
Willing to abstain from products / supplements enriched with Vitamin D
Willing to abstain from products / supplements enriched with plant sterols or stanols
Willing to abstain from products / supplements enriched with (β)glucans or fungi.

Willing to abstain from products / supplements that are mentioned to *boost your immune system*
Willing to abstain from (products enriched in) pre/pro-biotics

Exclusion criteria

Already received influenza vaccination in 2023
Allergy to mushrooms
Known allergic reaction to an active component or other components of the vaccine (e.g. Chicken Eggs)
Having donated blood within one month prior to the start of the study, or planning to donate blood during the study
Excessive alcohol use (>20 consumptions per week)
Regular use of soft and/or hard drugs
Using medication for diseases known to affect inflammation/immunity (e.g. inhaled corticosteroids and prednisone)

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:	Recruiting
Start date (anticipated):	14-09-2023
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	Na METC goedkeuring wordt het in ClinicalTrials.gov geregistreerd
CCMO	NL84275.068.23