Assessment of the risk of foodallergy from mealworm consumption

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- Establashing the percentage of patients within a population allergic to house dust mite and/or crustaceans, that can get an allergic reaction from consuming mealworm.- Establashing the risk of sensitization and allergy by handling mealworms and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON44120

Source
ToetsingOnline

Brief title
Assessment of the risk of foodallergy from mealworm-consumption

Condition

- Allergic conditions

Synonym
Food Allergy, mealworm allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,geld van NVWA via TNO;Innovation for Life;Zeist

Intervention

Keyword: crossreactivity, crustaceans, foodallergy, mealworm

Outcome measures

Primary outcome

Establashing the reactivity of patients allergic to crustaceans and/or house dust mite to mealworm, with direct BAT, CAP, immunoblot, skin prick test and foodchalenge with mealworm.

Establashing the reactivity of individuals that have symptoms after contact with mealworm, to mealworm, house dust mite and shrimp, with direct BAT, CAP, immunoblot, skin prick test and foodchalenge with mealworm and shrimp.

Secondary outcome

not applicable

Study description

Background summary

A lot of research is being done into the development and applicability to the food market of insect protein. This is an investment in a sustainable food market. Mealworm seems a good candidate. The introduction of new proteins comes with safety issues. One of the biggest risks is allerginicity. In theory every protein, allso new proteins in food can cause allergic reactions.
A pilot study shows crossreactivity between proteins in mealworm and crustaceans and house dust mite. These results ask for a more elaborate study into the sensibilisation potential of the proteins.

Study objective

- Establashing the percentage of patients within a population allergic to house dust mite and/or crustaceans, that can get an allergic reaction from consuming mealworm.
- Establashing the risk of sensitization and allergy by handling mealworms and

the change of (cross)allergy with crustaceans.

Study design

Part one:establashing the percentage of patients, within a crustacean and / or house dust mite allergic population, that can get an allergic reaction when consuming mealworm
1) Selection of patients with crustacean and / or house dust mite allergy
2) Visit 1: history, blood collection and skin prick test
3) Visit 2 and 3: foodchalenge with mealworm, unrecognisable

Part two: establashing the risk of an allergic reaction when consuming mealworm or shrimp, in individuals that have symptoms after contact with mealworm.
1) Recrutement of individuals that have symptoms after contact with mealworms
2) Visit 1: history and blood collection. this can be done at the place of work
3) Visit 2: blood collection and skin prick test at UMC Utrecht
4) Visit 3 and 4: foodchalenge with mealworm, unrecognisable
5) Visit 5: foodchalenge with shrimp

Intervention

food provocation

Study burden and risks

A first visit of 1 hour and a second visit with a chalenge of two times 9 hours for patients.
For individuals that have symptoms after contact with mealworms, first visit 30 minutes, at a location of choice, second 1 hour, possibly a third , forth and fifth visit, thirth and fourth of 9 hours each, fifth of 6 hours.
The risk of blood collection and intraveneus dripp (during food challenge) is a slight pain and the possibility of a bruise. Skin prick test is a safe test and is routinely done in the outpatient clinic. In most cases, the participant will get a weal (looks like a mosquito bite). The itching disappears after 15-30 minutes and the weal itself after 2-3 hours.
Food chalenge (selection of 15 patients and 5 patients) is done routinely at our daycare-facility. Our experiance shows us that most reactions seen are mild, a severe reaction is vary rare. Before the chalenge starts the participant will get an intraveneus dripp, to make sure mediation can be given quickly if nessessary. Allso the participant is under costant observation of trained nurses, under supervision of a mediacal doctor, up to five hours after the chalenge.

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

- age 18 years and older
- suspected history and serology of allergy to shrimp or house dust mite OR
- symptoms after contact with mealworms

Exclusion criteria

- congenital / aquired immune disorder
- lymfoproliferative disease
- use of systemic immune suppressants
- pregnancy
- use of beta-blockers

- severe asthma, defined as FEV1 < 70%

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2013
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-04-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-04-2015
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL43731.041.13