Genistein as an add-on treatment for CF?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24579

Source
Nationaal Trial Register

Brief title
The TRIO study

Health condition

Cystic Fibrosis, Taaislijmziekte, CF

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The main study parameter is pulmonary function (%FEV1) measured before and after the use of genistein and before and after the use of placebo.

Secondary outcome

· Sweat chloride concentration (SCC), before and after the use of genistein and placebo;

· Airway resistance (Rint and bodybox), before and after the use of genistein and placebo;

· BMI (=weight (in Kg)/Length2 (in cm)) before and after the use of genistein and placebo;

· Quality of life (measured with CFQ-questionnaire) before and after the use of genistein and placebo;

· Elastase measurements in the feces before and after the use of genistein and placebo;

· The CFTR stimulating ability of the concentration of genistein in the patient's blood samples, examined by in vitro testing (in the organoid model). We will also determine the plasma levels of genistein by HPLC;

Exploratory endpoint:

· Assessment of ß-adrenergic sweat secretion by evaporimetry, before and after the use of genistein and placebo.

Study description

Study objective

Adding genistein to Ivacaftor treatment leads to higher levels of restoration of the CFTR protein channel activity in patients with a mutation associated with residual CFTR function.

Study design

- Before placebo

- After using placebo for 8 weeks

- Before genistein

- After using genistein for 8 weeks

Intervention

Genistein or Placebo

Contacts

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Eligibility criteria

Inclusion criteria

· CFTR genotype: at least one S1251N mutation;

· Already had a rectal biopsy to produce an organoid;

· Use of Ivacaftor;

· Male and female patients, aged 6 years or older on the date of informed consent;

· Signed informed consent form (IC).

Exclusion criteria

· Use of genistein or curcumin at start or within four weeks prior to start of the study;

· Severe acute exacerbation or pulmonary infection during last four weeks (needing intravenous treatment and/or systemic corticosteroids);

· (History of) hypothyroidism;

· Women who are trying to become pregnant, or are pregnant or breastfeeding;

· Women with estrogen receptor-positive tumors;

· Postmenopausal women on anti-oestrogen therapy (like tamoxifen and aromatase

blockers) for estrogen-responsive breast cancer;
· Participation in another drug-investigating clinical study at the start or within four weeks prior to the start;

· Inability to follow instructions of the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-06-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-06-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45929
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6193
NTR-old	NTR6515
CCMO	NL57585.041.16
OMON	NL-OMON45929

Study results