

Curcumin study: Plasma concentrations of curcumin, piperin and genistein in subjects using over the counter supplements

Published: 30-08-2016

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The aim of this study is to investigate if curcumin is detectable when subjects use curcumin supplements in daily life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON42857

Source

ToetsingOnline

Brief title

Curcumin study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Vascular disorders NEC

Synonym

availability of curcumin in blood, Bioavailability of curcumin

Research involving

Human

Sponsors and support

Primary sponsor: Apotheek

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Concentrations, Curcumin, Over the counter, Plasma

Outcome measures

Primary outcome

Plasma concentrations

Secondary outcome

Brand, type and dosage of the used foodsupplements. Information about the medication patient use for regular care on the day of the visit.

Study description

Background summary

The interest in curcumin is growing and despite all the pre-clinical evidence the effectiveness in clinical trials is very limited. The food supplements with curcumin currently on the market as over the counter products are accompanied with large advertisements and probably fallacious claims about the bioavailability. The costs for these products are high and a price of 40-50 euros for one bottle is not uncommon. Despite all this patients are currently using this supplement as additional care.

In this pilot research we want to investigate which products, formulations and dosages patients use. We want to measure the plasma levels reached during intake of these food supplements. We also want to have more inside in the different food supplements patients use such as piperin and genistein.

Study objective

The aim of this study is to investigate if curcumin is detectable when subjects use curcumin supplements in daily life.

Study design

This is a study into curcumin food supplements taken by subjects in daily life. In which we aim to include 50 subjects.

The interventions in this study are:

- One questionnaire about the food supplement use by subjects
- Two blood samples will be collected, one before intake of their food supplement with curcumin and one after intake of the food supplement.

Study burden and risks

In this study no product is involved as intervention or additional to their daily routine. The only intervention that the including adult subject will undergo is a two times sampling of their blood and completion of a questionnaire.

Contacts

Public

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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 \geq 18 years
- Use of curcumin food supplement
- Able to give informed consent

Exclusion criteria

- Inability to give informed consent
- Inability to follow instructions of the investigator

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-11-2016

Enrollment: 50

Type: Actual

Ethics review

Approved WMO

Date: 30-08-2016

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 12-12-2016

Application type: Amendment
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25480

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL58755.018.16
OMON	NL-OMON25480