Metabolism of curcumin in healthy volunteers

Published: 12-06-2017
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To investigate the metabolism of curcumin in healthy volunteers and the effects of piprine and a lipid liquid formulation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON48906

Source
ToetsingOnline

Brief title
Metabolism of curcumin in healthy volunteers

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Therapeutic and nontherapeutic effects (excl toxicity)
- Vascular disorders NEC

Synonym
Bioavailability and metabolisme of curcumin

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Curcumin, lipid liquid formulation, Metabolism, Piperine

Outcome measures

Primary outcome

Kinetic parameters of curcumin: AUC, clearance, volume of distribution,

elimination half-life and possible Cmax and Tmax concentrations.

Secondary outcome

Kinetic parameters of curcumin and piperine of each of the 5 products.

Influence of curcumin and piperine on different biochemical parameters.

Study description

Background summary

The interest in curcumin is growing and despite all the pre-clinical evidence the effectiveness in clinical trials is sometimes limited. It is assumed that the clinical effect of curcumin is poor due to tis low bioavailability. Piperine or a lipid liquid formulation may increase the bioavailability of curcumin. We expect that also metabolism could play an important part. In this study we want to investigate the metabolism of curcumin further after controlled intake of curcumin and investigate the effect of piperine or a polysorbate formulation (as liquid lipid formulation) on the metabolism of curcumin.

Study objective

To investigate the metabolism of curcumin in healthy volunteers and the effects of piprine and a lipid liquid formulation.

Study design

Single center, open-label, randomised, cross-over intervention study.

Intervention

During 5 investigation fases, 5 different curcumin products will be taken orally. Each product will be taken once.

Study burden and risks

The risk is associated with this study is considered negligible.
The burden contains an screeningsvisit with an bloodwithdrawal.
The investigation contains 5 investigation fases. Each containing: three days following a diet, a hospital day of 9 hours with multiple bloodwithdrawals and a hospital visit the next day for 1 blood withdrawal and collection of urine samples.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Healthy male, age * 18 years
* Able to give written informed consent
* Willing to follow the dietary regimens
* Able to complete the entire study

Exclusion criteria

* Major illness in the past 3 months
* Gastrointestinal disease
* History of cholecystectomy or other bile duct abnormalities
* Metabolic or endocrine diseases
* Drug abuse or alcoholism (>3 units of alcohol per day)
* Use of prescription or non-prescription drugs and herbal or dietary supplements within 30 days prior to the first administration of curcumin supplement. With the exclusion of (non)prescription drugs used for their local effect and thus have no influence on the kinetics of curcumin.
* Use of tobacco products
* High usage of curcumin and black pepper in daily food/beverages
* Known intolerance for curcumin or black pepper
* Participation in another clinical trial in the 3 months prior to the start of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2018

Enrollment:	9
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2019
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: 23684
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61195.018.17
OMON	NL-OMON23684