To investigate the absorption and conversion of curcumin in the human body of healthy adult male patients

No registrations found.

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

Summary

ID

NL-OMON23684

Source
Nationaal Trial Register

Health condition

A study performed in healthy patients mainly focussing on the pharmacokinetics of curcumin and it's metabolites after oral intake.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam
Source(s) of monetary or material Support: Academic Medical Center (AMC) Amsterdam

Intervention

Outcome measures

Primary outcome

To investigate the kinetics and metabolism of curcumin over time in healthy volunteers after intake of different curcumin products and the effect of piperine and a lipid formulation.

Secondary outcome

To determine if addition of piperine increase the bioavailability of active curcumin and if there is a change in kinetic and metabolic profile.

To determine if a liquid commercial curcumin product, with a claimed 185x higher bioavailability, indeed increases the bioavailability of curcumin and if there is a change in kinetic and metabolic profile.

To investigate if a single dose of curcumin would influence different biochemical parameters.

Study description

Background summary

It is assumed that the clinical effect of curcumin is poor due to its low bioavailability and that piperine, or a lipid formulation may increase the bioavailability of curcumin. Nine healthy male volunteers aged 18 years or older are randomized in 3 arms. Each arm contains the following five formulations:

Curcumin-C3 complex 600 mg

Curcumin-C3 complex 2400 mg

Curcumin-C3 complex with piperine 2400/20 mg
Curcumine complex formulated in polysorbate 80

Curcumin complex formulated in a solid curcumin particles formulation
After intake bloodsamples, urine and feces will be collected over a certain timeframe. The following components will be analyzed by LC/MS/MS for pharmacokinetic parameters: curcumin + two other curcuminoids, tetrahydrocurcumin, piperine and the conjugated metabolites of the above mentioned components.

Study objective

We expect to find little to no uptake of curcumin in the central circulation.

Study design

Bloodsamples will be taken at T=0, t=0.25, t=0.5, t=0.75, t=1, t=1.5, t=2, t=4, t=8, t=24.

Urine willl be collected during 24 hours.

Feces will be collected during 48 hours.

Intervention

Curcumin-C3 complex 600 mg

Curcumin-C3 complex 2400 mg

Curcumin-C3 complex with piperine 2400/20 mg
Curcumine complex formulated in polysorbate 80
Curcumin complex formulated in a solid curcumin particles formulation

Contacts

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Eligibility criteria

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

- Inability to give informed consent

- Major illness in the past 3 months

- Gasrtointestinal disease that may influence the absorption of the supplements

- 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.

- 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

- Use of alcohol for at least 3 days prior to each study day

- Use of caffeine products for at least 3 days prior to each study day

- Strenuous exercise for at least 3 days prior to each study day, defined as more than 1 hour exercise per day

- Eating/drinking of grapefruit and grapefruit-containing products or star fruit for at least 3 days prior to each study day

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	9
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-10-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48906
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6552
NTR-old	NTR6741
CCMO	NL61195.018.17
OMON	NL-OMON48906

Study results