Evaluation of the absorption of colourless carotenoids and related compounds from food sources

First published: 01/02/2017

Last updated: 13/06/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS17479

Study ID

49603

DARWIN EU® study

No

Study countries

Spain

Study description

Apparently healthy human volunteers will follow a washout period in which they will refrain from eating foods rich in carotenoids. After this period they will eat a breakfast containing a tomato product and blood will be taken at t = 0 hours and during the following 10 hours. Weeks later, they will repeat the process, although on this occasion they will eat a breakfast containing a fruit juice. Faeces of the volunteers will be collected before and after the test breakfast.

Study status

Ongoing

Research institutions and networks

Institutions

Facultad de Farmacia - Universidad de Sevilla

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

ANTONIO J. MELÉNDEZ-MARTÍNEZ ajmelendez@us.es

Study contact

ajmelendez@us.es

Primary lead investigator

ANTONIO J. MELÉNDEZ-MARTÍNEZ

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 30/01/2014

Study start date
Planned: 07/06/2017

Actual: 07/06/2017

Date of final study report
Planned: 30/10/2024

Sources of funding

- Other

More details on funding

Consejería de Economía, Innovación, Ciencia y Empleo, Junta de Andalucía

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Information about the absorption of dietary compounds

Main study objective:

To assess the postprandial levels of carocarotenoids and related compounds after the ingestion of two different types of breakfasts containing carotenoid-rich products and evaluation of the presente of the compounds of interest in faeces before and after the test breakfasts.

Population studied

Age groups

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)

Estimated number of subjects

20

Study design details

Outcomes

Levels of compounds of interest in plasma, plasma lipoproteins and faeces after ingesting test meals.

Data analysis plan

The levels of colourless carotenoids, other carotenoids and related compounds (for example possible carotenoid metabolites) will be analyzed in plasma and faeces. The variables will be compounds of interest, the gender of participants and the carotenoid-rich foods provided in the test meals.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No