The effectiveness of vitamin D suppletion on improving symptoms of fatigue in children between 12 and 18 years old

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29083

Source
Nationaal Trial Register

Health condition

Fatigue

Sponsors and support

Primary sponsor: CWZ
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Primary endpoint of this study will be the difference in symptoms of fatigue as measured by the CIS-k, PedsQL and PedsQL fatigue questionnaire before and after vitamine D suppletion for three months. This will be matched to the calcidiol serum level at the start of inclusion.

Secondary outcome

The amount and characteristics of the children who manage to go from a calcidiol serum level of <75 nmol/L at the start of inclusion to >75 nmol/L after 3 months of vitamin D suppletion.

Study description

Background summary

An explorative pilot for determining the effectiveness of vitamine D on improving symptoms of fatigue in children between 12 and 18 years old. The amount of vitamin D will be determined by calcidiol levels at the start of inclusion.

Study objective

The calculated loading dose, follow by a daily dose of vitamine D will particularly improve symptoms of fatigue in patients with a calcidiol serum level below 50 nmol/L.

Study design

At t=0 the calcidiol serum level will be determined and the CIS-k, PedsQL and PedsQL fatigue questionnaire will be performed.
After 3 months of vitamin D suppletion, the child will revisit the hospital to determine the calcidiol serum level again and the CIS-k, PedsQL and PedsQL fatigue questionnaire will be performed once more.

Intervention

Vitamin D/colecalciferol

Contacts

Public
CWZ
Jasper Bos

0642536606
Scientific
CWZ
Jasper Bos

0642536606

Eligibility criteria

Inclusion criteria

- Children between 12 and 18 years old
- Referred to a hospital due to symptoms of fatigue
- Calcidiol serum level <100 nmol/L

Exclusion criteria

- Comorbidities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-10-2019
Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
n.a.

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7540
Other	CMO Arnhem-Nijmegen : 2019-5234

Study results

Summary results
n.a.