Nutrition/Interventional - NETHERLANDS

Competent authority

Contact Details

Contact Name 1

Central Committee for Research Involving Human Subjects/ Centrale Commissie Mensgebonden Onderzoek (CCMO)

Contact Name 2

F.a.o. Competent authority (CA)

Phone

+ 31 70 340 6700

Email General

ccmo@ccmo.nl

Email Department

bi@ccmo.nl

Address

PO Box 16302

ZIP/City

2500 BH The Hague

Country

Netherlands (NL)

Web address

http://www.ccmo-online.nl

Additional Information

NB! Email if CCMO acts as CA: bi@ccmo.nl

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Institutional Competent Authority
Institutional Ethics Committee
Regional Ethics Committee

Regulatory and ethics bodies involved in approval process for trials including patients

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Regulatory and ethics bodies involved in approval process for trials including including healthy participants

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Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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CA - Registration/ notification without approval required for

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	CA - Registration requirements for clinical trials Registration mandatory **Registration requirements for clinical trials including patients** – **Registration requirements for clinical trials including healthy participants** – **Registration requirements for clinical trials including vulnerable population** – **CA - Submission required to** National CA Institutional CA International CA **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Medical Research Ethics Committees MRECs/METCs **Web address** http://www.ccmo.nl/en/accredited-mrecs **Additional Information** Links to the 24 accredited MRECs/METCs and their contact data are provided on the CCMO website (see provided web address)
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** Yes **National declaration** available via regional ethics committees
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** International EC National EC Institutional EC **Ethical approval (favourable opinion) for trials including patients to be obtained from** – **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Single Opinion **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** –

Submission of Application	**Entitled to study submission** Sponsor Investigator Physician Dietitian Nutritionist PhD Industry National citizen **Entitled to submission of trials including patients** – **Entitled to submission of trials including healthy participants** – **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** available via regional ethics committees
Language of Submission	**Language(s) of application** English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 6 **Time in weeks from submission to positive approval (maximum)** 12

	Time in weeks from submission to positive approval (average) 8
Safety Reporting	**Investigator shall report SAE to** National CA Institution Sponsor Trial Coordinator Other **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist Pharmacist PhD **Entitled to be principal investigator for trials with patients** – **Entitled to be principal investigator for trials with healthy participants** – **Entitled to be principal investigator for trials with vulnerable population** –
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** No **Accepted format of Informed Consent (IC) form** Written consent **Accepted format of IC form for studies including patients** – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –

Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Elderly Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** Yes **Applicable ethical regulations** Not specified
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Compensation optional not mandatory **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** –
Funding	**Trials generally financially supported by industry** Yes **Funding is an issue during the approval process** Yes
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Obligation to contract a liability insurance for trials including patients for** – **Obligation to contract a liability insurance for trials including healthy participants for** –

Obligation to contract a liability insurance for trials including vulnerable population for

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Specific insurance companies - Additional information

There are no specific insurance companies

Insurance fee in € value indicated as

–

Insurance fee in € value indicated as

–

Quality Assurance/ Quality Control (QA/QC)

Regularly performed methods

Audits
Inspections
Monitoring
Standard Operating Procedures (SOP)
Case Report Form (CRF)

Regularly performed methods in trials including patients

–

Regularly performed methods in trials including healthy participants

–

Regularly performed methods in trials including vulnerable population

–

Standards concerning quality assurance and quality control exist

Yes

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

–

Regularly performed audits in trials including vulnerable population

–

Regularly performed audits - Additional information

Internal and external audits may be performed

Archiving & Data Management

Study documents must be kept at least (in years)

–

Legal framework for data management exists

Not specified

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki Other ethical principles for medical research (other than Declaration of Helsinki) ICH-GCP Guidelines **Applied regulatory conventions in studies including patients** – **Applied regulatory conventions in studies including healthy participants** – **Applied regulatory conventions in studies including vulnerable population** – **Applicable national laws** Hospital Act Data protection Act Medical device act Drug act **Applicable national laws for patients** – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Yes
Invasive Catheters	**Invasive catheters permitted** Yes