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Arginine supplementation in severe sepsis: effects on metabolism and microcirculation

Submission date	Recruitment status	[_] Prospectively registered
27/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2009	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR423; MEC 04-136

Study information

Scientific Title

Acronym
Arginine-sepsis study

Study objectives
NO synthesis is compromised during sepsis through lack of L-arginine and may thereby contribute to impaired microcirculation and organ dysfunction. Supplementation of L-arginine in septic patients can replete L-arginine deficiency and will improve microcirculation, vascular permeability, and organ function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sepsis, Septic shock

Interventions
1. 3 days intravenous L-arginine infusion
2. 3 days intravenous L-alanine (placebo) infusion

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Microcirculation

Secondary outcome measures
1. Arginine metabolism
2. Hemodynamics
3. Vascular permeability
4. Organ functions
5. Disease severity scores

Overall study start date
15/11/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Written informed consent from close relative
2. Age >18 years
3. Patient meets the general criteria for severe sepsis or septic shock (international published sepsis definitions), diagnosed less than 48 hours prior to study inclusion
4. Patient must be relatively hemodynamically stable, defined as stable blood pressure (variation in mean arterial pressure <15 mmHg) for 2 hours without necessity of increasing the vasopressor dose, inotropic support or rate of fluid administration
5. Systemic arterial catheter in place with continuous pressure monitoring
6. Patients in whom the clinician is prepared to provide full life support during the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
1. Shock due to any cause other than sepsis (e.g. drug reaction or drug overdose, pulmonary embolus, burn injury, severe blood loss etc.)
2. Prolonged or high dose corticosteroid use
3. Liver cirrhosis

4. Chronic pancreatitis
5. Insulin-dependent diabetes mellitus
6. Metastases, haematological, malignancies or chemotherapy
7. Patients on dialysis (CVVH or other)
8. Pre-existent urea cycle disorders or renal failure

Date of first enrolment
15/11/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Maastricht
Maastricht
Netherlands
6102 AZ

Sponsor information

Organisation
Nutrition and Toxicology Research Institute Maastricht (NUTRIM) (Netherlands)

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Sponsor type
Not defined

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Industry

Funder Name
Novartis Consumer Health B.V. (Netherlands) R&D Nutrition

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration