

Arginine supplementation in severe sepsis: effects on metabolism and microcirculation

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/08/2009	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Y.C. Luiking

Contact details
University Maastricht
Department of Surgery
P.O. Box 5800
Maastricht
Netherlands
6102 AZ
+31 (0)43 3874427
yc.luiking@ah.unimaas.nl

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)

Sponsor details

P.O. Box 616

Maastricht

Netherlands

6200 MD

+31 (0)43 3881476

m.grispen@nutrim.unimaas.nl

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