

# Arginine supplementation in severe sepsis: effects on metabolism and microcirculation

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

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

Microcirculation

**Key secondary outcome(s))**

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

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## 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)

**ROR**  
<https://ror.org/02jz4aj89>

## **Funder(s)**

**Funder type**  
Industry

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

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration