Long-term StaphyloCoccus aureus decolonizAtion in patients on home parentRal nutRition: a randomized multicEnter tRial.

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To identify the most effective and safe long-term S. aureus carriage decolonization strategy in HPN patients. Ultimately this willlead to less antimicrobial resistance, less catheter removals and lower mortality rates. Also, other chronic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON44280

Source
ToetsingOnline

Brief title
S. aureus decolonization in HPN patients/CARRIER-trial

Condition

- Gastrointestinal motility and defaecation conditions
- Bacterial infectious disorders

Synonym
contamination with own skin bacteria, S. aureus carriage

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: decolonization, home parenteral nutrition, intestinal failure, S. aureus

Outcome measures

Primary outcome

Primary outcome: proportion of patients eradicated for S. aureus (nose, throat,

rectum, exit-site catheter) during one year.

Secondary outcome

Secondary outcomes: long-term antimicrobial resistance, adverse events, patient

compliance, incidence of (S. aureus)

infections, catheter removals, mortality rates, S. aureus transmission routes,

quality of life and costs.

Study description

Background summary

Patients on home parenteral nutrition (HPN) are exposed to a life-long risk of developing S. aureus bacteremia (SAB). SAB
pose a threat to both catheter and patient survival and may lead to a permanent loss of vascular access. S. aureus carriage
eradication has proven successful in prevention of S. aureus infections. S. aureus decolonization is a key strategy to maintain
venous access and avoid hospitalization.

Study objective

To identify the most effective and safe long-term S. aureus carriage decolonization strategy in HPN patients. Ultimately this will
lead to less antimicrobial resistance, less catheter removals and lower

mortality rates. Also, other chronic patientgroups may
benefit from this trial as well, such as hemodialysis patients.

Study design

Randomized open-label multicenter trial in the Netherlands and Denmark.

Intervention

Patients will be randomized to a search and destroy (SD) strategy: a quick and short, systemic antibiotic treatment (nasal
mupirocin ointment, oropharyngeal chlorhexidine rinse, chlorhexidine body wash and systemic antibiotics) or a continuous
suppression (CS) strategy: a repeated chronic topical treatment (nasal
mupirocin ointment, oropharyngeal chlorhexidine rinse
and chlorhexidine body wash).

Study burden and risks

Burden
The burden will consist of every 6 monthly visits, as is the standard follow-up for HPN patients according to international HPN guidelines. Additionally, we will perform tests and obtain data (e.g. adverse events) after 3 and 9 months by the telephone. In case of unsuccessful eradication in the SD-strategy group an additional phone call (20 minuts) and performing extra culture swabs will be necessary. The expectation based on earlier experience is that it is a feasible treatment protocol and it has little impact on daily life.

Risks:
There are no additional risks in this study, since usual care is being followed in both strategies. The main 'known' risks associated with this study are the known side effects, allergies and/or toxicity of the various prescribed antibiotic drugs. It is currently uncertain which of the treatment strategies mentioned above is most effective and safe.

Benefit and group relatedness
HPN patients, and likely other chronic patient groups such as hemodialysis patients, will benefit from an evidence based effective long-term decolonization protocol. Ultimately such protocol will lower S. aureus infections and reduce subsequently hospitalizations, catheter removals, mortality, antimicrobial resistance and costs. Furthermore, this study provides guidance for further policy development and implementation of (longterm) S. aureus decolonization protocols and other novel infection/transmission preventive strategies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patient is fully able to understand the nature of the proposed intervention.
- Patient is diagnosed with intestinal failure and on HPN and/or fluid replacement
- Written informed consent by the patient before entering the trial.
- Age * 18 years.
- Estimated life expectancy * 1 year.
- Patient colonized with S. aureus.

Exclusion criteria

- Cannot be expected to comply with the trial plan (substance abuse, mental condition).
- Pregnant or breastfeeding women.

- Continuous exposure to MRSA (e.g. pig farmer).
- Allergy for chlorhexidine and betadine.
- No options for oral and/or topical antibiotics due to allergies and/or resistance.
- Active S. aureus infection.
- Currently on treatment with antibiotics active against S. aureus.
- Decolonization (including mupriocin) treatment in the previous two months.
- The presence of an unremovable nasal foreign body.
- AST and ALT levels more than five times the upper limit of normal or liver failure.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2018
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-03-2018
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-07-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT03173053
CCMO	NL61885.091.17

Study results

Date completed:	13-10-2021
Actual enrolment:	63

Summary results
Trial is onging in other countries