MRSA decolonization in complicated carriage - cluster randomized trial

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To determine the superiority of doxycycline-rifampicin compared to trimethoprim-rifampicin for the decolonization treatment of complicated MRSA carriership.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON51735

Source
ToetsingOnline

Brief title
CLEANEST

Condition

- Bacterial infectious disorders

Synonym
MRSA carriership - Methicillin resistant Staphylococcus aureus carriership

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Decolonization, Eradication, MRSA

Outcome measures

Primary outcome

The main study endpoint is the success rate of MRSA decolonization. Successful decolonization is defined as 3 consecutive negative cultures after treatment, with a minimum interval of 7 days.

Secondary outcome

- The long-term success rate of decolonization treatment of doxycycline-rifampicin compared to trimethoprim-rifampicin, defined as an additional set of negative MRSA swabs taken 2 months and 1 year after decolonization treatment.

- To determine whether there is an association between virulence factors and success rate of decolonization.

Study description

Background summary

MRSA decolonization has proven to prevent infection and reduce transmission. It has yet remained undecided which combination of anti-staphylococcal agents is most effective in the treatment of complicated MRSA carriage. A recent cohort study showed the highest success rate of decolonization in patients treated with doxycycline-rifampicin (86%) compared to the other antibiotic combinations (average 69%). However, because of the retrospective study design the validity of the results is limited. A randomized clinical study is necessary to determine if doxycycline-rifampicin is superior to other conventional treatment regimens. The Dutch guideline recommends both doxycycline-rifampicin and trimethoprim-rifampicin as first choice treatments for decolonization of complicated MRSA carriage. Therefore trimethoprim-rifampicin will be the comparator of this study.

Study objective

To determine the superiority of doxycycline-rifampicin compared to trimethoprim-rifampicin for the decolonization treatment of complicated MRSA carriership.

Study design

Multicenter open-label cluster randomized controlled trial.

Intervention

Group A: doxycycline 200 mg q.d. - rifampicin 600mg b.i.d. versus Group B: trimethoprim 200mg b.i.d. - rifampicin 600mg b.i.d. All orally, total duration 7 days.

Study burden and risks

MRSA decolonization treatment is already standard clinical practice in the Netherlands. There is no additional burden or risk associated with participation in the study. Both antibiotic regimens (in Group A and Group B) used in the study, are recommended as first-line therapy by the Dutch guideline for the treatment of MRSA carriage. The study is open label, so there is no additional risk of blinding. The number of outpatient visits and follow-up cultures are not different from daily clinical practice in the Netherlands. No invasive procedures will be performed for the purpose of this study.

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

complicated MRSA carriership
Adult

Exclusion criteria

- catheters/drains in situ
- Failure of previous decolonization attempt of complicated MRSA carriage
- Allergy or other contra-indication to either doxycycline, rifampicin or trimethoprim (these patients will participate in the observational arm)
- Previous participation in this study
- Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2022
Enrollment:	201
Type:	Actual

Ethics review

Approved WMO Date:	28-03-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-04-2024

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL79720.058.21