IMPACT study

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27681

Bron
Nationaal Trial Register

Verkorte titel
IMPACT

Aandoening

stewardship
antimicrobial
cluster randomized trial
multicenter

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: ZON MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Lenth of hospital stay

Toelichting onderzoek

Achtergrond van het onderzoek

Summary

Antimicrobial resistance is an important health care problem. Antibiotic stewardship programs aim to curb the increasing antimicrobial resistance rate. Quality assurance of appropriate antibiotic use is one of the cornerstones of these programs. Various methods can be used to evaluate the current quality of antibiotic use in hospitals, ranging from continuously monitoring overall antibiotic use at an institutional level, to performing point-prevalence studies in which appropriate use in individual patients is assessed. These methods have never been compared and the (cost) effectiveness of these various options in measuring and feeding back information on antibiotic use is unknown. The question is whether monitoring of overall use suffices, or whether labor intensive and costly point prevalence studies are more effective and cost-effective in improving the quality of antibiotic use.

STUDY OBJECTIVE

The primary objective of this study is to assess the (cost-)effectiveness of antimicrobial stewardship interventions in Dutch acute care hospitals with a special focus on the difference in effect between three methods to measure and feed back information in improving the quality of antibiotic use:

1. OVERALL USE - Retrospectively collect data on overall antibiotic use (pharmacy data), including the use of "reserve" antibiotics, over a 12 month period. Drug use data will be standardized in DDDs and DOT and fed back per cluster.

2. PPS-QI: Perform point prevalence studies (PPS) to collect data on appropriate antibiotic use in individual patients as defined by a set of validated quality indicators for appropriate use of antibiotics (PPS-QI), as developed by our group. This information on the quality of antibiotic

use will
be fed back per cluster.

3. PPS ECDC-HAI: Perform a simplified point prevalence studies (PPS) at the various wards in which
data are collected on a non-validated, simpler set of indicators (PPS-ECDC. This information on the
quality of antibiotic use will be fed back per cluster.

Our second objective is to assess the influence on the outcome measures of additional factors
improving the quality of antibiotic use, including hospital factors, A-team factors and factors regarding the locally tailored Stewardship interventions (e.g. type of intervention, number of interventions, time investment and use of the worksheet implementation steps)

METHODS AND DESIGN

To assess the (cost) effectiveness of these various methods, a cluster randomized, multicenter trial
(clustered RCT) will be performed in 21 Dutch hospitals. Each hospital will be divided into two clusters: surgical and non-surgical. A total of 42 clusters will be randomly allocated to one of three
methods, stratified by hospital (i.e. in each hospital, each strategy will be allocated to no more than
one cluster).

We will retrospectively collect from patient charts, four times with one month interval before and
four times after the measurements with the subsequent Antibiotic team (A-team) interventions, data
on 25 patients per cluster treated with antibiotics for >24hours: age, sex, co-morbidity, type of
infection, length of hospital stay (LOS), ICU admission, hospital mortality and antibiotic use (agents,
route and treatment duration). By means of a questionnaire we will collect information on hospital
characteristics, A-team characteristics and specifications on the implemented stewardship activities,
including type of activity and time investment.

MEASUREMENTS & FEEDBACK

In all three scenarios, information is collected (respectively on overall antibiotic use, results

of the
PPS-QI and PPS-ECDC), compared with similar clusters from other hospitals and fed back to the local
A-teams in the form of a report. This way, it is likely that clusters with high respectively low overall
antibiotic use (scenario 1) or high respectively low quality of antibiotic use (scenario 2 and 3) are
easily recognizable in the report.

MULTI-FACETED IMPROVEMENT STRATEGY

A Multi-Faceted Strategy (MFS), including one educational meeting, provision of feedback reports
and worksheets, one outreach visit and reminders, is used to support participating hospitals to
systematically develop and implement tailored Stewardship interventions in order to improve the
appropriateness of antibiotic use in their hospital.

A face to face educational meeting is organized, in which antibiotic teams receive instructions on the
interpretation of feedback reports and usage of the worksheet. The worksheet is provided to
systematically guide A-teams through the process of identifying improvement foci, assessing local
barriers and defining tailored Stewardship interventions to overcome these barriers and improve the
appropriateness of antibiotic use in their hospital. A-teams receive the feedback reports together
with the worksheet after the educational meeting.

Throughout the intervention period, the study team (D-team) guides and advices on the
implementation of improvement strategies based on the needs of the local A-teams. One outreach
visit is organized, during which the D-team and A-teams use academic detailing to discuss local
barriers and help to define an improvement plan, containing tailored Stewardship activities that can
be implemented on the participating departments. Email reminders are sent and advice is given by
phone or email if requested by the A-team.

OUCOMES

The primary endpoint for evaluation of study outcomes and comparison of study arms is length of hospital stay (LOS). Secondary endpoints are: total antibiotic use and use of restricted
antibiotics, expressed in DOT per 100 admissions or per 100 patient-days (agents, route and treatment duration), admission to and duration of intensive care unit (ICU) stay, hospital mortality,
and costs (costs associated with health care utilization, costs related to the measurement of antibiotic use resp. performance of the PPS (D-team) and costs related to the stewardship interventions (A-team)).

ANALYSIS: SAMPLE SIZE AND STATISTICS

With 21 hospitals with each 2 clusters, with 4 times 25 patients per cluster before and 4 times 25
patients per cluster after, the total sample size will be 8400 patients. Assuming a within cluster
correlation (ICC) of 0.20 and a baseline Length of Stay (LOS) of 9 days (SD 6.2) (based on length of
stay in recent studies), this study will have a power of approximately 80% to demonstrate a reduction
in geometric mean LOS of 0.8 day (-9%) with an alpha of 0.05.

Differences between the pre- and post-intervention periods, with a focus on differences between the
three study methods, will be evaluated for length of stay and other numerical endpoints using mixed
linear models. These models account for within-cluster dependencies, and allow adjustment for
confounders. For dichotomous outcomes generalized estimating equation models will be used.

The effect of additional factors (including hospital factors, A-team factors and factors regarding the
locally tailored Stewardship interventions) on LOS and secondary outcome measures will be evaluated for those factors that show a sufficient (>15%) variation between hospitals.
The key question for the economic evaluation is to estimate the costs associated with the three
different strategies to measure antibiotic use in the hospital setting, differentiating between study
costs, implementation costs and operational costs, and to offset these costs with potential benefits
of more labor intensive strategies in terms of improved antibiotic prescribing and shorter hospital

stays.

Doel van het onderzoek

The primary objective of this study is to assess the (cost-)effectiveness of antimicrobial stewardship interventions in Dutch acute care hospitals with a special focus on the difference in effect between three methods to measure and feed back information in improving the quality of antibiotic use. Our second objective is to assess the influence on the outcome measures of additional factors improving the quality of antibiotic use, including hospital factors, A-team factors and factors regarding the locally tailored Stewardship interventions (e.g. type of intervention, number of interventions, time investment and use of the worksheet implementation steps).

Onderzoeksopzet

pre-assessments (February – March – April – May 2015)

post-assessments (February – March – April – May 2017)

Onderzoeksproduct en/of interventie

feedback and implementation in 42 clusters (21 hospitals)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

the hospital should have an antibiotic stewardship team

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

no antibiotic stewardship team

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	8500
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-04-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5577
NTR-old	NTR5933
Ander register	METC : E2-170

Resultaten