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Dental care REsistance prevention and Antibiotic prescribing Modification the DREAM trial

Submission date
10/04/2013

Recruitment status
No longer recruiting

Registration date
30/04/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Although primary care dentists are generally aware of problems related to antibiotic resistance, in German dental primary care antibiotics are prescribed too often. Qualitative open-ended interviews and group discussions with primary care dentists showed that there are multiple reasons. Uncertainty (e.g. related to recent changes concerning the prophylaxes of endocarditis), perceived prescription pressure of patients suffering from severe pain (especially during emergency services), and unawareness play a major role here. The DREAM trial will test an intervention that aims at optimizing the prescription of antibiotics in dental care.

Who can participate?
The DREAM trial will include more than 50 dentists of the German region of Mecklenburg-Western Pomerania. Participating dentists will provide data on the amount of patients they take care of as well as on the number of antibiotics prescribed. This information will be derived from dentists practice software systems. All together, information on more than 46,000 patients will be included and scientifically analyzed. In addition, microbiological analyses will be performed within a subgroup of patients suffering from oral infections. These analyses will give insights into the level and development of microbial resistance.

What does the study involve?
During three six-month periods of data collection, information on the number of patients and antibiotic prescriptions will be collected. After the first data collection period, dentists will be randomly allocated to the intervention or control group. Dentists of the intervention group will attend a training session that aims at optimizing antibiotic prescribing. Dentists of the control group will provide care as usual. The antibiotic prescription rates of the two groups will be compared. Further, patients included in the subgroup of microbiological analyses will be asked to provide oral swabs at three different points in time. During a telephone interview, these patients will also be asked to provide information on the duration of treatment, the use of medical services, re-consultation, pain, and adverse effects related to antibiotic treatment.

What are the possible benefits and risks of participation?
Patients of the intervention group might benefit from their doctors increased awareness towards unnecessary antibiotic prescriptions. In the best case, patients benefit from more appropriate antibiotic prescribing. It is unlikely that the trial will harm patients.

Where is the study run from?
Institute of General Practice, the Clinic for Tooth Conservation and Periodontology, and the Department of Medical Microbiology, Virology and Hygiene, all located at the Rostock University Medical Center, Germany. The three institutions form one study centre.

When is the study starting and how long is it expected to run for?
The recruitment of dentists started in September 2012. Data collection started in January 2013 and will be finished by December 2014. The project is expected to run until March 2015.

Who is funding the study?
Funding is provided by the German Federal Ministry of Health (Bundesministerium für Gesundheit, BMG).

Who is the main contact?
Dr. Christin Löffler
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Study website
http://allgemeinmedizin.med.uni-rostock.de/index.php?id=119

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Dental care REsistance prevention and Antibiotic prescribing Modification A cluster-randomised controlled trial in German dental primary care

Acronym
DREAM

Study objectives
The DREAM trial will test the effectiveness of a multifaceted educational intervention aiming at the reduction of inappropriate antibiotic prescribing in dental primary care. Care as usual serves as control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics protocol was approved by the ethics committee of the University Medical Center Rostock (Ethikkommission an der Medizinischen Fakultät der Universität Rostock) on 18th December 2012. The reference number is A 2012-0147.

Study design
Two-arm single-centered cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Patient information can be found at http://allgemeinmedizin.med.uni-rostock.de/fileadmin/user_upload/DREAM_Infoblatt_Patienten_ohne_Unterschrift.pdf

Health condition(s) or problem(s) studied
Antibiotic prescribing in dental primary care

Interventions

The intervention involves elements of local consensus formation, antibiotic prescription feedback, and communication training. Training of the intervention group will be organized within small group sessions.

Control: Care as usual

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Dentists overall antibiotic prescription rate. Data is collected over a six-month baseline period (T0), at T1 (month 10 to 15), and T2 (month 19 to 24)

Secondary outcome measures
Secondary outcomes for the subgroup:
1. Severity of illness
2. Pain (VAS)
3. Duration of treatment
4. Re-consultation rate
5. Use of medical services
6. Adverse effects related to antibiotic treatment

Overall study start date
01/09/2012

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Primary care dentists and their male and female patient population of all ages in Mecklenburg-Western Pomerania (Germany).
2. Patients aged 18 years or older seen by their dentists for an odontogenic infection or abscess, and who have not been treated for such a condition in the previous six months, are eligible for being recruited into the subgroup (swabs).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
46.000 patients in 56 dental practices

Key exclusion criteria
To investigate antibiotic prescribing the DREAM trial includes the entire patient population of participating dental practices.

Exclusion criteria for patients in the subgroup include:
1. Younger than 18 years
2. Not being able to give informed consent (e.g. in case of dementia)
3. Consulting the dentist during the emergency service
4. Suffering from immunosuppression or malignoma
5. Having a disease-related life expectancy of less than 12 months

Date of first enrolment
01/09/2012

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin Rostock
Rostock
Germany
18055

Sponsor information

Organisation
Medical University of Rostock (Universitätsmedizin Rostock) (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.med.uni-rostock.de

ROR
https://ror.org/03zdwsf69

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/02/2014		Yes	No