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The invasive dentistry - endocarditis association study

Submission date	Recruitment status	[X] Prospectively registered
06/07/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/06/2022	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Infective endocarditis (IE) is a serious infection of the heart. Around 30% of those who get IE die in the first year and survivors develop serious on going complications. Bacteria from the mouth are the cause in 35-45% of cases but it is not clear if these enter the blood during daily activities such as chewing food and tooth brushing, in those with poor oral hygiene, or during invasive dental procedures (IDP) e.g. extractions, dental scaling or root canal treatment. Because of the possible link to IDP, the focus of IE prevention has been to give antibiotics to those at risk of IE before any IDP. This is called antibiotic prophylaxis (AP) and is the standard of care for people at high-risk of IE in most of the world. However, there has never been a clinical trial to test if AP works. Because of this, NICE (National Institute for Health & Care Excellence) recommended that AP stop in 2008 and the UK is now the only country where AP is not recommended for patients at high-risk of IE. A recent study, however, found a significant increase in IE following introduction of the 2008 NICE guideline. This has raised serious concerns about the advice not to give AP in the UK. However, for AP to be effective there must be a causal link between IDP and IE, and the purpose of this study is to determine if there is a link or not.

Who can participate?
Patients who has an IDP performed and have their details entered in either the Hospital Episode Statistics Database or NHS Business Services Dental Database.

What does the study involve?
This study looks at patient details in two national databases and uses the information contained to track every patient that has had a IDP performed to investigate whether they develop IE or not over the following year. Researchers then look at this data to see whether IE occurs more frequently in the three months directly after a IDP is performed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
September 2016 to June 2021

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Professor Martin Thornhill

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
HTA 15/57/32

Study information

Scientific Title
The Invasive Dentistry - Endocarditis Association case-crossover study

Acronym
The IDEA Study

Study objectives
The IDEA-Study will link national data on courses of dental treatment and hospital admissions for infective endocarditis (IE) to investigate if there is a temporal link or association between invasive dental procedures and the development of IE.

Hypothesis:
1. Our Null hypothesis is that: There is no temporal association between invasive dental procedures and the development of IE. If the null hypothesis is proven, this would suggest there

is no rationale for AP and AP is unlikely to be effective in preventing IE. It would suggest other prevention strategies, such as improving oral hygiene, are likely to be more effective in preventing IE
2. Our alternative hypothesis is that: There is a temporal association between invasive dental procedures and the development of IE.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Because this study will only utilise publically available national data that have been linked and anonymised by the Health and Social Care Information Centre (HSCIC) before being made available to us, it will not require NHS ethics approval via NRES. It will, however, require us to apply through HSCIC's Data Access Request Service (DARS) to use the data. As part of this process we also need approval from the Data Access Advisory Group (DAAG). DAAG is an independent group, hosted by HSCIC, which considers applications for sensitive data made to the HSCIC's Data Access Request Service.

Study design
A case-crossover design study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Infective endocarditis

Interventions
This is an observational study using UK national databases to see if infective endocarditis hospital admissions occur with higher frequency in the 3 months immediately following a course of treatment at a dentists that includes an invasive dental procedure than in later 3 month control periods.

Using personal details to link 2 national databases every patient who has an IDP performed will be identified and tracked them see if they develop IE or not over the following year.

If IDP are linked to IE, researchers expect IE cases to peak in the 3 months after an IDP (since IE develops within 3 months of infection with a causal bacteria). If instead, activities such as tooth brushing enable oral bacteria to cause IE, IE cases are expected to be evenly spread throughout the year.

Comparisons will also be made as regards to the occurrence of IE following a visit to the dentist that includes an IDP with the occurrence following a visit that does not include an IDP.

Dental visits are identified because dentists complete a form for each patient they treat and send it to the NHS Business Service Authority in order to be paid. This records patient details and the types of dental procedure performed, including IDP, during each visit.

Intervention Type
Other

Primary outcome(s)
The incidence of infective endocarditis (IE) hospital admissions in the 3 months immediately following courses of dental treatment that includes an invasive dental procedure, coopered to the incidence of IE hospital admissions during later 3 month periods (3-6, 6-9 and 9-12 months after)

Key secondary outcome(s))
1. The frequency of courses of dental treatment involving an invasive dental procedure (cases) before an IE diagnosis
2. The frequency of course of dental treatment that did NOT involve an invasive dental procedure
The two outcomes are then compared.

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. All IE hospital admissions in England between 1st April 2010 and 31st March 2016 recorded on the Hospital Episode Statistics database
2. All individuals within England who attended an NHS dentist for a check up or treatment between 1st April 2009 and 31st March 2016 and whose data is recorded on the NHS Business Services Dental Database

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Individuals falling into the target population without a known NHS number
2. Individuals with missing or corrupt records

Date of first enrolment
01/09/2016

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2TA

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	results and plain language summary in Health Technology Assessment	01/05/2022	08/06/2022	Yes	No