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Comparison of two different wound-care treatments used after dental extractions to identify if healing was improved and pain reduced

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
26/11/2021

Overall study status
Completed

Last Edited
15/07/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Two existing treatments have been used in a specialist clinic following tooth extraction for several years. The level of pain and speed of healing following tooth removal was recorded over a 14 year period and the benefit of the two treatments compared. A treatment using ultra-low concentration chlorinated water reduced the likelihood of dry socket by over 30x and it was concluded that this treatment produced a significant improvement over the other to such an extent that this treatment was adopted exclusively by the clinic.

Who can participate?
Outpatient dental extractions in a specialist dental clinic in the UK between 2000 and 2014.

What does the study involve?
Routine out-patient dental extractions were carried out, and following the extraction, the patient had the site managed with sterile saline mouth-rinse or irrigation of the socket with very low dose aqueous chlorine with saline.

What are the possible benefits and risks of participation?
Both treatments are known and accepted wound-care treatments and adopted for many decades. There was an expectation that there would be a difference in the incidence of alveolar osteitis following extraction. The principal benefit is the prevention of alveolar osteitis and avoidance of antibiotic use and improved antibiotic stewardship.

Where is the study run from?
A private dental specialist clinic near Cambridge (UK)

When is the study starting and how long is it expected to run for?
January 2000 to December 2014.

Who is funding the study?
This is self funded via the clinic as an audit to help improve clinical outcomes for patients.

Who is the main contact?
Dr Myles Dakin, myles.dakin@hypo-stream.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical audit of two standard surgical site treatments following dental extractions and the impact on incidence of alveolar osteitis within a specialist dental clinic

Acronym
CAAO

Study objectives
There is no difference in post dental extraction healing when two existing wound healing treatments are used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval is required as the study was a retrospective analysis of two existing, licensed wound-care products used in treatment of burns injuries and non-healing leg ulcers. The two treatments are licensed over the counter products and reported on for over four decades. i.e. this is a comparison of two existing OTC wound care formulations.

Study design
Single centre retrospective clinical audit

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available (retrospective study)

Health condition(s) or problem(s) studied
Post dental extraction alveolar osteitis

Interventions
Use of one of two standard, existing, licensed wound-care treatments at time of dental extraction: sterile water rinse plus corsodyl rinse or socket irrigation with very low level hypochlorite in normal saline.

Patient records from January 2000 to May 2014 were analysed to audit the use of the above.

Intervention Type
Procedure/Surgery

Primary outcome measure
Incidence of alveolar osteitis post-operatively measured using patient records at a single time point

Secondary outcome measures
Satisfactory healing without pain measured using patient records at a single time point

Overall study start date
02/01/2000

Completion date
20/12/2014

Eligibility

Key inclusion criteria
Patients attending an out-patient dental clinic for non-acute dental extractions.

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
934

Total final enrolment
401

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2000

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Specialst Dental Partners Ltd
Unit 9 Beech House
Melbourn Science Park
Melbourn
Cambridge

United Kingdom
SG8 6HB

Sponsor information

Organisation
Specialist Dental Partners Ltd

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Sponsor type
Hospital/treatment centre

Website
http://www.specialistdentalpartners.co.uk

Organisation
Hypo-Stream Ltd

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
BMC Oral Health

Intention to publish date
02/02/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Myles Dakin, Specialist Dental Partners, Unit 9 Beech House, Melbourn Science Park, Melbourn, Cambridgeshire SG8 6HB.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		14/12/2021	15/07/2022	No	No