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ARIX: the effectiveness of group Acupuncture in the treatment of Radiation Induced Xerostomia (dry mouth)

Submission date	Recruitment status	[_] Prospectively registered
29/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/04/2015	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
ARIX: a randomised phase III crossover trial to examine the effectiveness of group Acupuncture in the treatment of Radiation Induced Xerostomia

Acronym
ARIX

Study objectives
To determine whether patients suffering with chronic radiation induced xerostomia experience a reduction in key xerostomia symptoms following treatment with acupuncture in a group setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton East Research Ethics Committee, 15/09/2009, ref: 09/H1107/81

Study design
Interventional multicentre randomised phase III crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic radiation-induced xerostomia

Interventions
Intervention 1:
Nurse/radiographer specialist-led educational package in oral care (control). Two group sessions, weeks 1 and 5, and follow up for 6 months.

Intervention 2:
Group acupuncture. Eight weekly group sessions, weeks 1 - 8, follow up for 6 months.

Patients are randomised equally to either intervention 1, or intervention 2. Four weeks after completion of treatment they crossover to receive the alternate intervention.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Patient reported change in severity of chronic dry mouth.

Outcomes will be measured at the following timepoints for each intervention: baseline (before delivery of intervention), week 5, week 9, then once more 6 months after completion of acupuncture.

Secondary outcome measures
1. Change in severity of other key xerostomia symptoms (sticky saliva, dry lips, difficulty swallowing, problems with sense of smell, waking at night, need to sip water to relieve a dry mouth, need to sip water to help swallow food)
2. Change in total salivary output measured using Schirmer strips
3. Benefits of regular group meetings to aspects of quality of life for patients experiencing chronic xerostomia
4. Health economic evaluation

Outcomes will be measured at the following timepoints for each intervention: baseline (before delivery of intervention), week 5, week 9, then once more 6 months after completion of acupuncture.

Overall study start date
15/10/2009

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Patients treated with radical radiotherapy for head and neck cancer at least 18 months previously
2. At least one parotid gland within field of radiotherapy
3. Patient complains of xerostomia
4. No clinical sign of local recurrence
5. Age 18 years or over, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 patients

Key exclusion criteria
1. Xerostomia caused by reason other than radiotherapy, e.g., Sjogren's disease
2. Previous surgery to more than one parotid gland
3. Currently using pilocarpine
4. Previous acupuncture treatment for this condition
5. Any physical characteristics that could prevent, or complicate, correct needle insertion

Date of first enrolment
15/10/2009

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Cancer Centre
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
Brighton and Sussex Medical School (UK)

Sponsor details
c/o Mr Scott Harfield
Royal Sussex County Hospital
Research & Development Directorate
Clinical Investigation & Research Unit

Eastern Road
Brighton
England
United Kingdom
BN2 5BE

Sponsor type
Hospital/treatment centre

Website
http://www.bsuh.nhs.uk/

ROR
https://ror.org/01qz7fr76

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C54/A7374)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Results article	results	01/03/2013		Yes	No