

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

Submission date 29/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/11/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/04/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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