

Lugol's Iodine in surgical management of epithelial dysplasia in the oral cavity and oropharynx

Submission date 10/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/04/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/08/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-lugols-iodine-during-surgery-to-remove-abnormal-cells-from-the-mouth-lister>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

McCaul 01/2014

Study information

Scientific Title

A multi-centre, randomised controlled trial assessing the effectiveness of Lugol's Iodine in Surgical management of Epithelial dysplasia in the oral cavity and oropharynx

Acronym

LISTER

Study objectives

Does intraoperative visualisation of dysplastic mucosa with Lugol's Iodine assist in improving accuracy of excision of epithelial dysplasia of oral cavity and oropharynx?

Ethics approval required

Old ethics approval format

Ethics approval(s)

London-Harrow Research Ethics Committee, 13/10/2016, ref: 16/LO/0857

Study design

Prospective multicentre phase III randomised controlled clinical 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

Epithelial dysplasia in the oral cavity and oropharynx

Interventions

1. Standard Treatment Group: Surgical excision of epithelial dysplasia as per usual practice
2. Intervention Treatment Group: Surgical excision of epithelial dysplasia assisted by visualisation with Lugol's iodine

Intervention Type

Procedure/Surgery

Primary outcome measure

Rates of surface dysplasia or carcinoma-in-situ at surface mucosal margins

Secondary outcome measures

1. Two-year incidence of histologically confirmed transformation to SCC in the oral/cavity /oropharynx
2. Occult SCC diagnosed histopathologically in excised mucosa
3. Surface area of mucosa excised
4. Extent of margin clearance in mm
5. Surgeon decision to re-excise at the same site following positive margins
6. Estimate of the two year recurrence rates of oral dysplasia
7. Acceptability of the technique to surgeons (intervention treatment group)
8. Safety of the technique (intervention treatment group)
9. Assessment of Quality of Life changes

Overall study start date

01/01/2014

Completion date

01/06/2019

Eligibility**Key inclusion criteria**

1. Provision of written informed consent
2. Age \geq 18 years old
3. Epithelial dysplasia of the oral cavity or oropharynx, undergoing primary surgical excision under general anaesthesia

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 (to increase to 388 after initial feasibility)

Key exclusion criteria

1. Previous surgery or radiotherapy for head and neck cancer
2. Allergy to iodine
3. Previous diagnosis of head & Neck SCC in the past 5 years or active malignancy within 2 years of randomisation (except basal cell carcinoma or carcinoma of the cervix in-situ)

Date of first enrolment

01/12/2015

Date of final enrolment

01/12/2018

Locations**Countries of recruitment**

England

Scotland

United Kingdom

Study participating centre

London North West Healthcare Trust

Northwick Park Hospital

United Kingdom

HA1 3UJ

Study participating centre

Bradford Royal Infirmary

Duckworth Lane

Bradford

United Kingdom

BD9 6RJ

Study participating centre**North Manchester General Hospital**

The Pennine Acute Hospitals NHS Trust

D Block Square, Level 4

Delaunays Road, Crumpsall

Manchester

United Kingdom

M8 5RB

Study participating centre**Ninewells Hospital and Dundee University Medicals**

Dundee

United Kingdom

DD1 9SY

Study participating centre**Queen Elizabeth Hospital**

1345 Govan Road

Glasgow

United Kingdom

G51 4TF

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

Sponsor details

West Glasgow Ambulatory Care Hospital

Dalnair Street

Glasgow

Scotland

United Kingdom

G3 8SW

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

Oracle Cancer Trust

Results and Publications

Publication and dissemination plan

The findings will be disseminated locally at clinical governance meetings, at national and international head and neck cancer scientific meetings (BAOMS, BAHNO, IAOO). We will take advice from our local patient research forum on how to best reach the local population with the findings. We aim to publish the findings in the British Journal of Oral and Maxillofacial Surgery within six months of the final patient visit.

Intention to publish date

01/06/2020

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.2	27/02/2017	09/08/2022	No	No
HRA research summary			28/06/2023	No	No