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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	[_] Prospectively registered [X] Protocol
Registration date 01/04/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/08/2022	**Condition category** Cancer	[_] Individual participant data [_] 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

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Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Prospective multicentre phase III randomised controlled clinical trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

Completion date
01/06/2019

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Scotland

Study participating centre
London North West Healthcare Trust
Northwick Park Hospital
United Kingdom
HA1 3UJ

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
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Study participating centre
North Manchester General Hospital
The Pennine Acute Hospitals NHS Trust
D Block Square, Level 4
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Study participating centre
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Study participating centre
Queen Elizabeth Hospital
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Oracle Cancer Trust

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.2	27/02/2017	09/08/2022	No	No