

Lugols Iodine in Head and Neck Cancer Surgery

Submission date 09/01/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-using-dye-during-surgery-for-mouth-and-throat-cancer-LIHNCS>

Contact information

Type(s)

Scientific

Contact name

Dr James A McCaul

Contact details

Bradford Teaching Hospitals NHS Foundation Trust
St Lukes Hospital
Little Horton Lane
Bradford
United Kingdom
BD5 0NA

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jim.mccaul@btinternet.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

McCaul 01/2007

Study information

Scientific Title

A multi-centre, randomised controlled trial assessing the effectiveness of Lugol's Iodine to assist excision of moderate dysplasia, severe dysplasia and carcinoma in situ at mucosal resection margin of oral and oropharyngeal squamous cell carcinoma.

Acronym

LIHNCS

Study objectives

Lugol's iodine demonstrates dysplastic cells at the margins of oral cavity and oropharynx Squamous Cell Carcinoma (SCCa). Data from our pilot study have suggested that using this technique allows surgeons resecting these tumours to identify and remove dysplastic tissue at the time of cancer resection. Using Lugol's stain reduced dysplasia at tumour margins from 32% to 2.7%; $p=0.001$ (95% CI 15.35 - 43.24). This should reduce local recurrence rates for this cancer type and site.

As of 10/12/2010, this record has been updated as funding has been secured to now roll this out as a larger multicentre trial. All updates to this record can be found in the relevant sections under the above update date. At this time, the anticipated start and end dates of the pilot study were extended to incorporate the main study; the initial details of the pilot study are as follows:

Initial anticipated start date: 01/03/2007

Initial anticipated end date: 01/06/2008

Please also note that the previous target number of participants for the pilot study was 164 participants, a further 300 will then be recruited for the main study.

As of 20/01/2011, the scientific title for this trial has been updated. The previous title was: "A prospective, multi-centre, randomised controlled trial looking at the effectiveness of Lugol's Iodine to assist excision of marginal dysplasia at resection of oral and oropharyngeal squamous cell carcinoma".

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Pilot study approval: Northern and York Multicentre Research Ethics Committee (MREC) on 09/02/2007
2. Main study approval: Leeds (East) Research Ethics Committee on 26/08/2010 (ref: 10/H1306/29)

Study design

Randomised controlled blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Squamous cell carcinoma of the oral cavity and oropharynx

Interventions

Application of a mucolytic agent and then 1.25% iodine prior to surgery. Control group uses no stain.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lugols Iodine

Primary outcome measure

Current information as of 10/12/2010:

Rates of surface dysplasia, carcinoma-in-situ or carcinoma at surface mucosal margins in the Lugols treated group versus gold standard management. Subgroup analysis of T1 and T2 versus T3 and T4 primary tumours.

Initial information at time of registration:

Incidence of moderate to severe dysplasia or carcinoma in situ at resection margins, assessed immediately after resection.

Secondary outcome measures

Current information as of 10/12/2010:

1. Acceptability of the technique to surgeons carrying out surgery for oral cavity and oropharynx cancer
2. Effect of Lugols technique on any further treatment carried out (radiotherapy or further surgery)
3. Estimate of the two year locoregional recurrence rates in each group
4. Mean and range of volume of tissue removed by each method

Initial information at time of registration:

Five year local recurrence rates.

Overall study start date

01/11/2010

Completion date

31/10/2014

Eligibility

Key inclusion criteria

Current information as of 10/12/2010:

1. Written informed consent obtained
2. Patient is at least 18 years old
3. Histological diagnosis of squamous cell carcinoma
4. Oral or oropharyngeal primary
5. Patient for surgical resection of primary tumour

Initial information at time of registration:

Patients with squamous cell carcinoma of the oral cavity or oropharynx, undergoing primary surgery.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

Current information as of 10/12/2010:

1. Previous surgery, chemotherapy or radiotherapy for head and neck cancer
2. Known allergy to iodine
3. Distant metastases (positive neck nodes are not an exclusion)
4. Nasal, nasopharyngeal or occult primary carcinoma
5. Previous diagnosis of cancer in the past 5 years (except basal cell carcinoma or carcinoma of the cervix in situ)

Initial information at time of registration:

1. Previous surgery or radiotherapy for head and neck cancer
2. Documented allergy to iodine containing preparations

Date of first enrolment

01/11/2010

Date of final enrolment

31/10/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Bradford Teaching Hospitals NHS Foundation Trust

Bradford

United Kingdom

BD5 0NA

Sponsor information

Organisation

Bradford Teaching Hospital NHS Foundation Trust (UK)

Sponsor details

Research and Development Department

Bradford Royal Infirmary

Duckworth Lane

Bradford

England

United Kingdom

BD5 0NA

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john.wright@bradfordhospitals.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.bradfordhospitals.nhs.uk/>

ROR

<https://ror.org/05gekvn04>

Funder(s)

Funder type

Charity

Funder Name

Local Trust Research Funds

Funder Name

Bradford Teaching Hospitals

Funder Name

Leeds Teaching Hospitals

Funder Name

Southern General Hospital Glasgow

Funder Name

Added 10/12/2010:

Funder Name

Cancer Research UK (CRUK) (UK)

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?
Protocol article	protocol	24/09/2013		Yes	No
Abstract results	results abstract	20/05/2017		No	No