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Lugols Iodine in Head and Neck Cancer Surgery

Submission date 09/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/10/2007	**Overall study status** Completed	
Last Edited 03/10/2018	**Condition category** Cancer	

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

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Additional identifiers

Protocol serial number
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 Lugols 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Current information as of 10/12/2010:
1. Acceptability of the technique to surgeons carrying our 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.

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

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD5 0NA

Sponsor information

Organisation
Bradford Teaching Hospital NHS Foundation Trust (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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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