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Research Update Report for Endowments sub-committee

Name: Mr Andrew Lyons Report for endowment committee March 2022

Title of project:

**Can genomics predict dysphagia after head and neck radiotherapy?**

A retrospective case-controlled cohort study using Genome Wide Association (GWAS) to compare genomic differences between head and neck cancer patients who do and do not suffer from severe swallowing and mouth opening difficulties after radiotherapy or chemoradiotherapy.

Endowment meeting when grant was awarded: 26 March 2014

Date endowment grant was paid: £10,000 paid on 6 August 2015

£20,000 paid on 3 October 2016

£29,462 paid on 24 April 2018

**Reopened study in December 2021**

(Study closed by joint research management office and all participating hospitals in March 2020 –all non-Covid studies affected). NIHR Badged.

**Eligible patients**

* 16 English radiotherapy departments
* All those who are alive and cancer free more than 2 years after treatment by radiotherapy +/- chemotherapy alone with no surgery at all either pre-radiotherapy or for recurrent disease
* I,000 eligible patients who consented to participate.

**Phase 2** **Pilot Clinic for Blood and saliva samples and clinical assessment**

* Prior to March 2020 research clinics were run at RLH (AL, IH and SF/NFORC staff)

for eligible patients from North Middlesex, UCLH, Barts, and Guys

97 Attended in person; and

33 who could not attend received saliva kits in the post and returned these to NFORC/SF with a repeated the Sydney swallow scale. Several needed multiple reminders (Kit costs > £30 each time ignoring staff time)

Therefore 97 with full clinical data, blood and/or saliva; and

33 with partial clinical data and saliva

They were evaluated for fibrosis post radiotherapy:

At clinic tests

* Fibrosis score – scale - unhelpful
* **inter incisal distance GOOD**
* repetitive swallow test – how many dry swallows in 30 seconds minute - unhelpful
* 100ml swallow test – Time taken and number of swallows - unhelpful

**Out of clinic**

* Trismus quality-of-life – scale unhelpful
* **Trismus reported by patient**
* **Swallow - Sydney swallow scale (SSQ) reported by patient** (PPI chose SSQ rather than MDADI)
* Osteoradionecrosis – Problems with this: Patients self-reporting an episode that settled with medical management; Most only happen after tooth extractions

**Results of Pilot Clinic**

* Grading of SSQ score > 1,000
* Grading inter incisal distance less than 3 cm with self-reported trismus as well
* Proven osteoradionecrosis no precipitating factor and permanent bone exposure

**Methods**

Subdivided into:

* severe at least 2 out of 3 positives (Trismus, SSQ, ORN)
* normal no positives
* Intermediate only one positive and that is less

**Patients**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| site | severe | mild | Intermediate | Total |
| Oropharynx | 22 | 35 | 17 | 74 |
| Oral | 2 | 0 | 2 | 4 |
| Nasopharynx | 2 | 3 | 5 | 10 |
| Hypopharynx | 1 | 1 | 3 | 5 |
| Supraglottis | 0 | 10 | 1 | 11 |
| Larynx Glottis | 1 | 13 | 5 | 19 |

Sinus 2 pts

Nose 1 pt

Unknown 4

**Delivered so far**

Run a wide a genome wide data collection with:

1. First test on 2 saliva samples to check radiotherapy has not corrupted salivary gland quality of data or insufficient material to analyse. Succeeded
2. Analysis of all clinical data collected and stratification into normal radiation response, severe radiation response and intermediate radiation response. Done
3. Run a genome wide data collection on all 130 patient samples. Now

**Now run Phase 3 in 12 other hospitals**

1. But now we need a bioinformatician / Statistician who can analyse genomic data against clinical data to identify candidate Snips
2. This analysis would be a comparison of severe against normal; across the whole continuum of the data; and against large publicly available genetic databanks
3. Publish immediately
4. In parallel Liaise with 12 remaining sites

Refresh PI and main trial coordinator there

Reopen Trial at these sites JRMO and research ethics

Offer authorship on first paper

1. Run Phase 3 with saliva only, no clinic unless patient can’t produce saliva then order blood collection