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# Study of the effect of platelet rich plasma (PRP) on the healing of skin grafts placed on radial forearm donor sites in patients being treated for head and neck cancer

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| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>12/02/2018 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Mark McGurk

**Contact details**
Oral Surgery
23rd Floor
Guy's Tower
Guy's Hospital
St Thomas' Street
London
United Kingdom
SE1 9RT
+44 (0)20 7188 4349
mark.mcgurk@kcl.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
N0013146160

# Study information

### Scientific Title
Study of the effect of platelet rich plasma (PRP) on the healing of skin grafts placed on radial forearm donor sites in patients being treated for head and neck cancer

### Study objectives
To see if a concentrated preparation of growth factors found in your blood cells speeds up the healing of a skin graft placed at the site a skin flap has been raised from your forearm.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised open label controlled parallel group trial

### Primary study design
Interventional

### Secondary study design
Randomised parallel trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied
Head and neck cancers

### Interventions
A Randomised Controlled Trial. New patients will be recruited from the head and neck clinic who present requiring surgical treatment of their oral cancer involving reconstruction with a skin only radial forearm flap. These patients will be randomised to a treatment group and a control group. Treatment group PRP applied to donor site before skin graft is sutured using standard protocol. Control group no PRP applied. It is not necessary to blind either the patients or the investigators to the treatment.

Follow-up standardised digital clinical photographs, from fixed distance with a grid, will be taken of the skin graft at 5 set post operative intervals. These will be evaluated by 2 independent clinicians blinded to the treatment groups. The primary end point is complete graft failure. The secondary end point is the degree of graft failure as a percentage of the whole flap. All patients will be monitored as per standard head and neck protocol until all wounds have healed.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
1. Rate of healing of the skin grafts
2. Reduction of skin graft failures

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
02/01/2004

### Completion date
02/01/2006

## Eligibility

### Key inclusion criteria
New patients attending the Head and Neck Oncology clinic at Guy's Hospital with a cancer requiring surgical excision and reconstruction with a skin only radial forearm flap

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
Not provided at time of registration

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
02/01/2004

### Date of final enrolment
02/01/2006

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Guy's Hospital**
London
United Kingdom
SE1 9RT

## Sponsor information

### Organisation
Department of Health

### Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

### Sponsor type
Government

### Website
http://www.dh.gov.uk/Home/fs/en

## Funder(s)

### Funder type
Government

### Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK)

**Funder Name**
Own account

**Funder Name**
NHS R&D Support Funding

# 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