

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised open label controlled parallel group trial

Study type(s)

Treatment

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(s)

1. Rate of healing of the skin grafts
2. Reduction of skin graft failures

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Guy's Hospital

London

United Kingdom

SE1 9RT

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration