

The Effect of Enteral Administration of Synbiotics Upon Infection Rates in Major Burns

Submission date 23/02/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/06/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/06/2010	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

2005-004541-34

Protocol serial number

2005-004541-34

Study information

Scientific Title

Study objectives

Provision of an enteral supply of synbiotics to patients with major burns will reduce the high incidence of infections

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the South Manchester Research Ethics Committee on 12/08/2005, reference number: 05/Q1403/141

Study design

Multicentre randomised double-blind controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major burn injury

Interventions

Two equal randomised groups, investigational medicinal product (IMP) group will be given a synbiotic cocktail comprising 10^{11} of each of 4 probiotic strains and 4 prebiotics. The control group will be given only the 4 prebiotics. The IMP and control will be identically packaged and will be administered twice daily throughout the inpatient admission by either oral or gastroenteral administration.

Added 01/06/10: trial stopped in 2006 (objectives no longer viable).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Infection rates (pre-defined definitions)
2. Antibiotic requirements
3. Changes in the microbiological composition of faeces

Key secondary outcome(s)

1. Mortality rate
2. Nutritional assessment
3. Insulin requirements
4. Assessment of gastrointestinal (GI) function
5. GI side effects
6. Fluid requirements
7. Haematologic and biochemical trends
8. Acute physiology scores
9. Healing times
10. Burn depth progression rates
11. Length of intensive care unit (ICU) and hospital stay
12. Mobilisation times
13. Activities of daily living independence times
14. Post-burns scarring assessment
15. Cost analysis

Completion date

10/03/2009

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

Adults (≥ 16 years) with $\geq 15\%$ total body surface area (TBSA) burn

Children (< 16 years) with $\geq 10\%$ TBSA burn

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients sustaining injuries that behave fundamentally differently to thermal burns (chemical burns, electrical burns and non-burns (e.g. staphylococcal scalded skin syndrome etc.)
2. Major non-burn trauma in addition to a major burn injury
3. Patients whose presentation is delayed > 12 hours post-injury
4. Severely immunocompromised
5. Post-transplant patients
6. Altered physiology (pregnant patients, children < 1 year old)
7. Patients opting out of the study

- 8. Terminally ill, not receiving aggressive treatment
- 9. Patients who have recently participated or are participating in other clinical studies will be evaluated on a case by case basis to evaluate the risk to the patient, and any bias, which may be introduced to either study
- 10. Patients with gastrointestinal failure, requiring >24 consecutive hours of total parenteral nutrition

Date of first enrolment

10/03/2006

Date of final enrolment

10/03/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Northwest Regional Burns Unit

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

South Manchester University Hospitals NHS Trust (SMUHT) (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Government

Funder Name

South Manchester University Hospitals NHS Trust (SMUHT) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration