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

Submission date	Recruitment status
23/02/2006	Stopped
Registration date	**Overall study status**
19/06/2006	Stopped
Last Edited	**Condition category**
01/06/2010	Injury, Occupational Diseases, Poisoning

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] 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

EudraCT/CTIS number
2005-004541-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
10/03/2006

Completion date
10/03/2009

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Adults (≥16 years) with ≥15% total body surface area (TBSA) burn
Children (<16 years) with ≥10% TBSA burn

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

50+

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
England

United Kingdom

Study participating centre
Northwest Regional Burns Unit
Manchester
United Kingdom
M23 9LT

Sponsor information

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

Sponsor details
c/o Dr Andrew Maine
Head of the Research and Development Directorate
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

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

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