

Quality of minor surgery carried out in primary or secondary care: population based randomised controlled equivalence trial

Submission date 25/04/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/08/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 95/25/03

Study information

Scientific Title

A prospective randomised comparison of minor surgery in primary and secondary care

Acronym

MiSTIC (Minor Surgery Trial In the Community)

Study objectives

Increasingly with the move towards a "primary care led NHS" services previously provided within hospitals are being provided within primary care settings. One such service is minor surgery. Although minor surgery is widely practised in primary care it has not been subjected to critical analysis in a randomised study in terms of its safety, quality and cost effectiveness. This study is a prospective, randomised controlled trial comparing the treatment of minor surgical conditions in primary and secondary care in terms of these variables.

Please note that the target number of participants was added as of 02/12/2008.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South and West Regional Research Ethics Committee, approved on 06/10/1999 (ref: 092/99)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Lesions requiring minor surgery (predominantly skin)

Interventions

Interventions amended as of 02/12/2008:

Elective minor surgeries in the categories described in the participants inclusion criteria field,

delivered either in primary care, by the patient's own GP or by referral to a primary care colleague, or in hospital, by either surgeons or dermatologists at a variety of grades.

Previous interventions:

Quality of surgery performed in primary care vs surgery performed in hospital

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Primary outcome measures amended as of 02/12/2008:

Quality of treatment measured using cosmetic results of surgery.

Previous primary outcome measures:

Safety, quality and cost effectiveness.

Secondary outcome measures

Added as of 02/12/2008:

1. Extent to which samples were sent for histology
2. Completeness of excision of malignant lesions
3. Patient satisfaction with aspects of care

Overall study start date

01/05/1999

Completion date

30/04/2002

Eligibility

Key inclusion criteria

Inclusion criteria amended as of 02/12/2008:

All patients (both genders, no age limits) with one of a range of conditions amenable to minor surgery who were considered suitable for treatment by a participating GP or one of their partners. The study focuses on four categories of minor surgical treatment; excisions, incisions, aspirations and "other", including removal of foreign bodies.

Previous inclusion criteria:

Patients requiring minor surgery.

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

490

Key exclusion criteria

Added as of 02/12/2008:

1. Patients whom operating doctor considered too complex for treatment in primary care
2. Patients requiring cautery
3. Patients requiring injections for the treatment of painful joints

Date of first enrolment

01/05/1999

Date of final enrolment

30/04/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Southampton Clinical Trials Unit

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.soton.ac.uk/>

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No