Towards appropriate outpatient follow-up of patients with chronic disease

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date		Statistical analysis plan		
23/01/2004	Completed Condition category	[X] Results		
Last Edited		[] Individual participant data		
01/04/2009	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof John Williams

Contact details

School of Postgraduate Studies in Medical & Health Care Maes-y-Gwernen Hall Morriston Hospital Swansea United Kingdom SA6 6NL +44 (0)1792 703531 John.williams@pgms.wales.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PSI05-11

Study information

Scientific Title

Acronym

OPFUS

Study objectives

The aim of the study was to evaluate open access as a means of following-up patients with chronic, relapsing, inflammatory bowel disease. The study sought to establish the clinical impact and cost effectiveness of open access follow-up in outpatients of patients with chronic disease, using inflammatory bowel disease as the exemplar.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised 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

Inflammatory bowel disease

Interventions

- 1. Open access follow-up in outpatients
- 2. Standard care

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Generic (36-item Short Form Health Survey [SF-36]) and disease-specific (UK Inflammatory Bowel Disease Questionnaire [UKIBDQ]) quality of life measured at six-monthly intervals for two years
- 2. Number of primary and secondary care contacts
- 3. Total resource use
- 4. Views of patients and general practitioners (GPs)

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/1995

Completion date

01/07/1999

Eligibility

Key inclusion criteria

180 adult patients (78 Crohn's disease, 77 ulcerative or indeterminate colitis, 25 ulcerative or idiopathic proctitis recruited from outpatient clinics between October 1995 and November 1996:

- 1. Aged over 18 years, either sex
- 2. Inactive or mildly active but stable inflammatory bowel disease

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

180

Key exclusion criteria

- 1. Active disease requiring treatment
- 2. Stoma
- 3. Other disease which required regular follow up
- 4. Unable to comply with data collection

Date of first enrolment

01/04/1995

Date of final enrolment

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre
School of Postgraduate Studies in Medical & Health Care
Swansea
United Kingdom
SA6 6NL

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (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	26/02/2000		Yes	No