An update on the Research Registry and IDEAL Studies

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IDEAL Conference 2017

New York Academy of Medicine

IDEAL Collaboration

RESEARCH REGISTRY

Overview

- Progress at the Research Registry
- IDEAL studies registered
- Concluding remarks
- Discussion

**no specific disclosures*


RESEARCH REGISTRY
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Registration Date
Details
Research Registry UIN
Primary Investigator
Title of Research
May 03, 2017 23:08
view
researchregistry2485
Mustafa Berkesoglu
Prognostic Effects of the Parameters and Different Nodal Systems in Patients with Gastric Cancer
May 03, 2017 20:55
view
researchregistry2484
Gitonga Munene
An Unusual Case of Jaundice: Biliary Tumor Thrombus in Fibrolamellar Hepatocellular Carcinoma.
May 03, 2017 19:43
view
researchregistry2483
Francesco Sadile
Histological fibrosis may predict the failure of core decompression in the treatment of osteonecrosis of the femoral head.

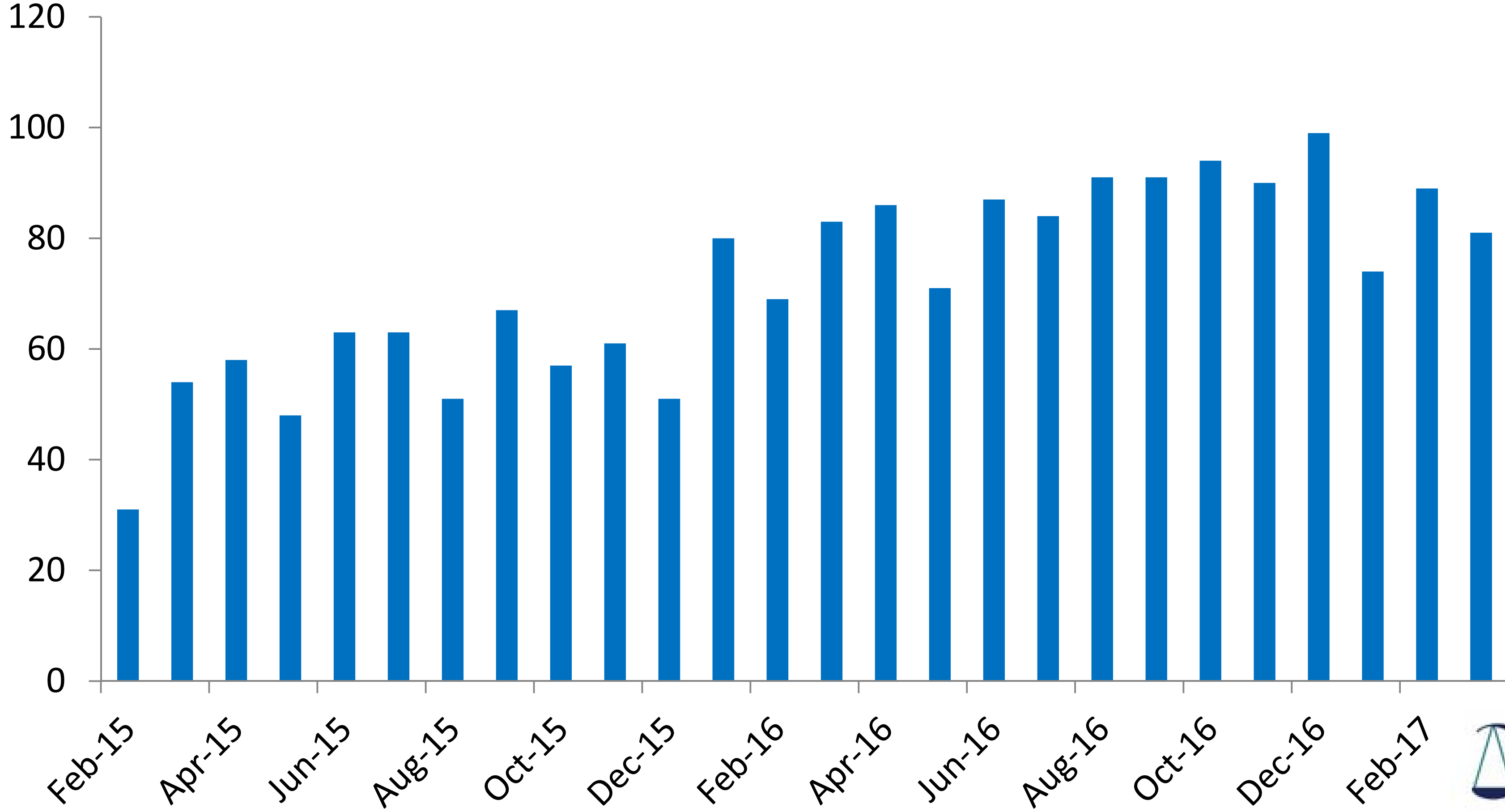
Summary Stats

Over 2,000 registered studies

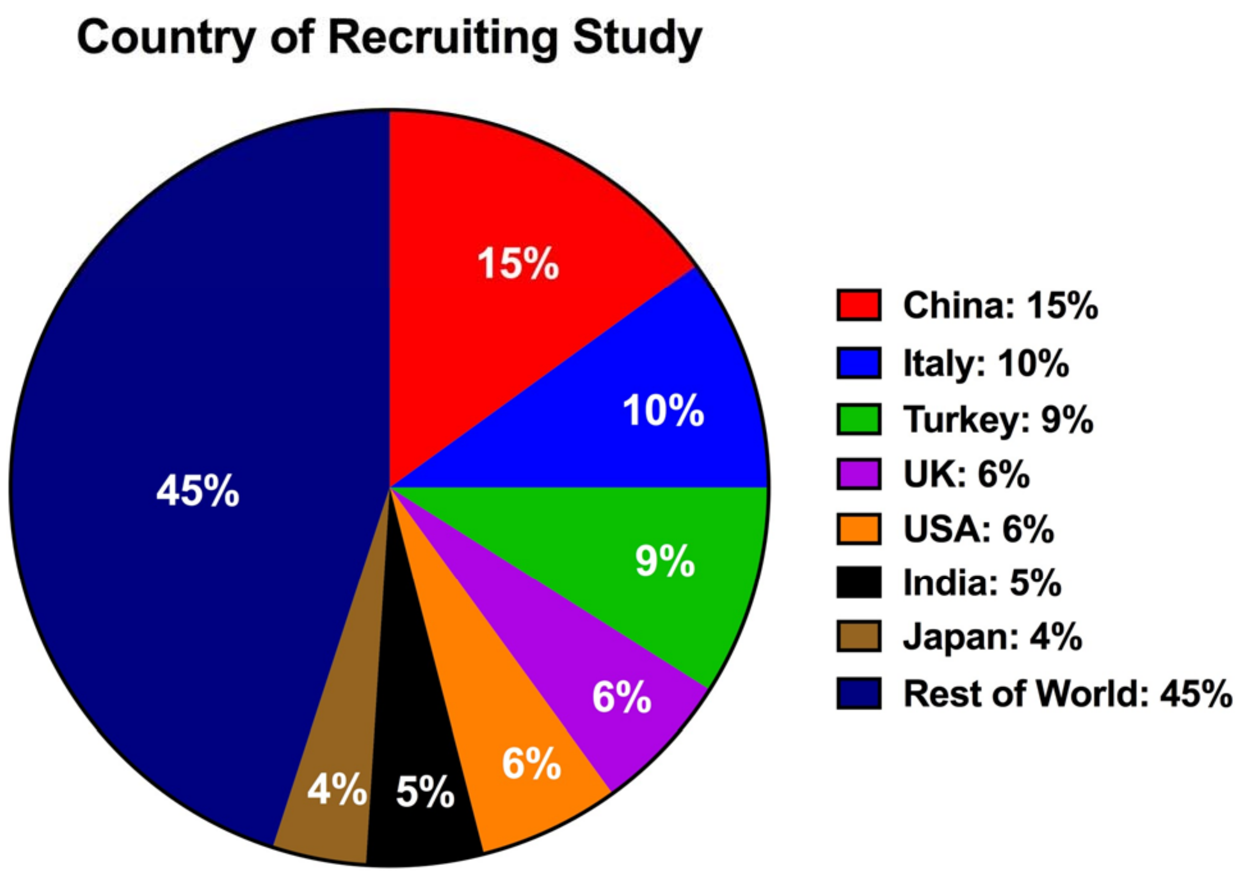
8+ million patients

Registration from 80+ countries

Monthly Registrations



Where are registrations coming from?



Medical Device Clinical Trials (monitoring period 1 January 2015 to 30 June 2015)

	August 2015		January 2016	
Total number of medical device trials with a FO during the reporting period	169		169	
Total number of medical device trials identified on a publicly accessible database at the end of the monitoring period	82	48%	144	85%
Of the total number registered, those found on ISRCTN	14	(8%)	20	(12%)
Of the total number registered, those found on clinicaltrials.gov	68	(40%)	88	(52%)
Total number of medical device trials not registered but details of the trial could be found on the UKCRN site	19	11%	27	(16%)
Of the total number registered, those found on researchregistry.com*			9	(5%)
The number of medical device trials that could not be found or not know to have registered; (breakdown of response to these below)	68	40%	25	15%
Of the medical device trials not found or not known to have registered: Reply received			6	(24%)
Of the replies received, those which stated that registration not yet required (e.g trial not yet recruited / trial not yet started / trial terminated before recruitment commenced)			5	(83%) Of those where reply received
Of the medical device trials not found or not known to have registered: No reply received			19	(76%)

Health Research Authority

Clinical Trials other than CTIMPs or Medical

	August 2015		January 2016	
Total number of other trials with a FO during the reporting period	300		300	
Total number of other trials found on a publicly accessible database	144	48%	240	80%
Of the total number registered, those found on ISRCTN	75	(25%)	86	(36%)
Of the total number registered, those found on clinicaltrials.gov	69	(23%)	94	(39%)
Total number of other trials not registered but details of the trial could be found on the UKCRN site	36	12%	48	(20%)
Of the total number registered, those found on researchregistry.com*			11	(5%)
German clinical trials database			1	(0.5%)
The number of other trials that could not be found or not known to have registered	120	40%	60	20%
Of the other clinical trials not found or not known to have registered: Reply received			33	(55%)
Of the replies received, those which stated that registration not yet required (e.g trial not yet recruited / trial not yet started / trial terminated before recruitment commenced)			9	(27%) Of those where reply received
Of the other clinical trials not found or not known to have registered: Reply not received			27	(45%)

A wide range of registrations

Scottish Participation in Genomics England 100,000 Genomes Project - Multicentre Scotland

Using behavioural insights to increase the return rate of HIV self-sampling kits - Public Health England

SMOOTH: Self-Management Open Online Trials in Health [Protocol]: An Analysis of Existing Online Trials - International Multicentre Study

Decreased Transport Time to the Surgical Intensive Care Unit Cedars-Sinai Medical Center

Pilot study of tremor disruption in Parkinson's Disease and tremor disorders – Cambridge University Hospitals

The Effects of Made-To-Measure Compression Garments on Pressures Exerted on t Lower Limbs and Recovery from Muscle Damage in Rugby Players - GSK Human Performance Lab, Brentford, UK

A wide range of registrations

Patient Experience of recovering from pneumonia – a qualitative longitudinal interview study - Nottingham University Hospitals NHS Trust

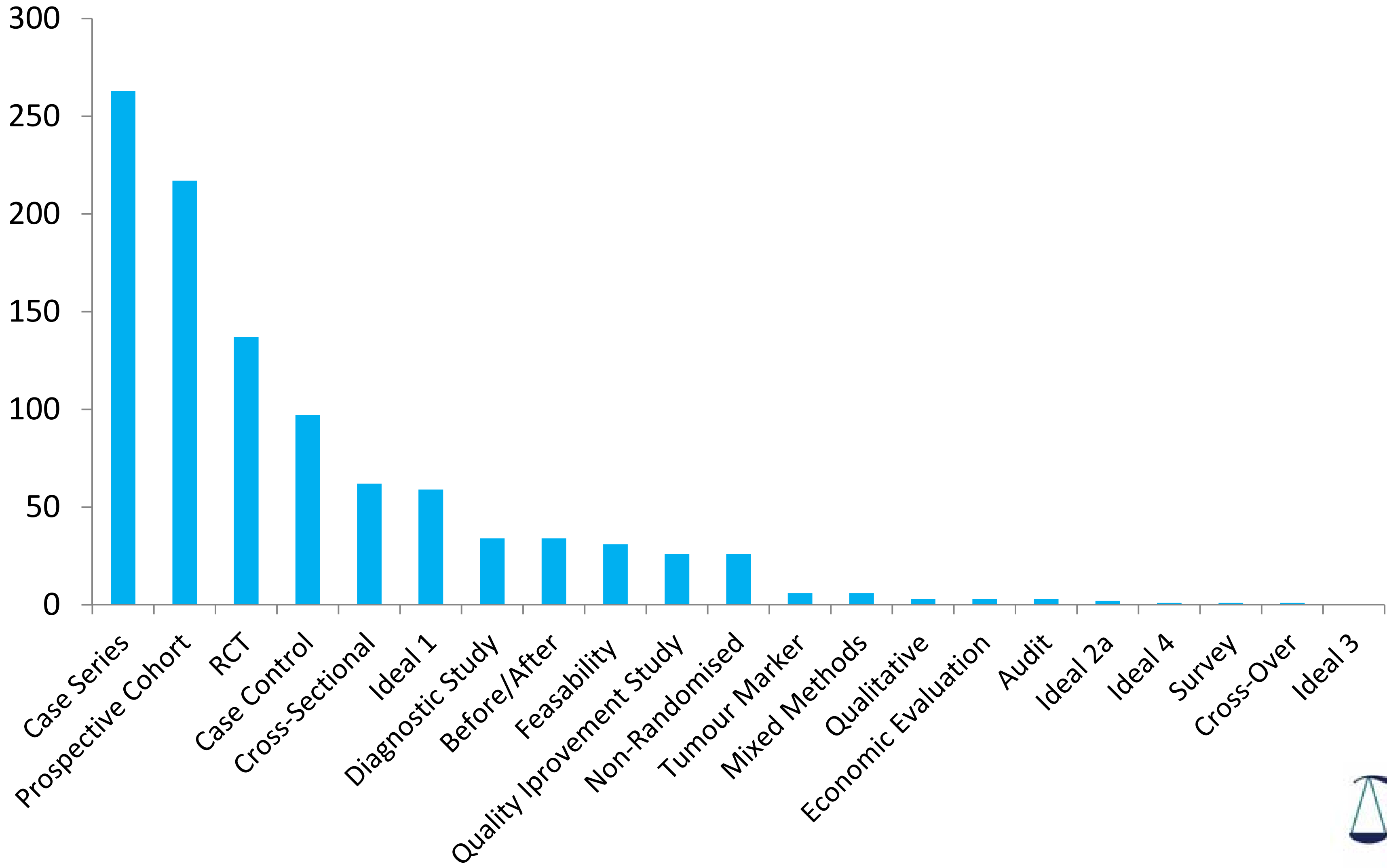
Healthy Choices Made Easy - Public Health England

The Implementation of New Health Promotion Services (Smoking Cessation, Weight Management and Alcohol Intervention) in an NHS Walk in Treatment Centre for Minor Injuries and Illnesses: a feasibility study using mixed methods - University of Portsmouth, U.K

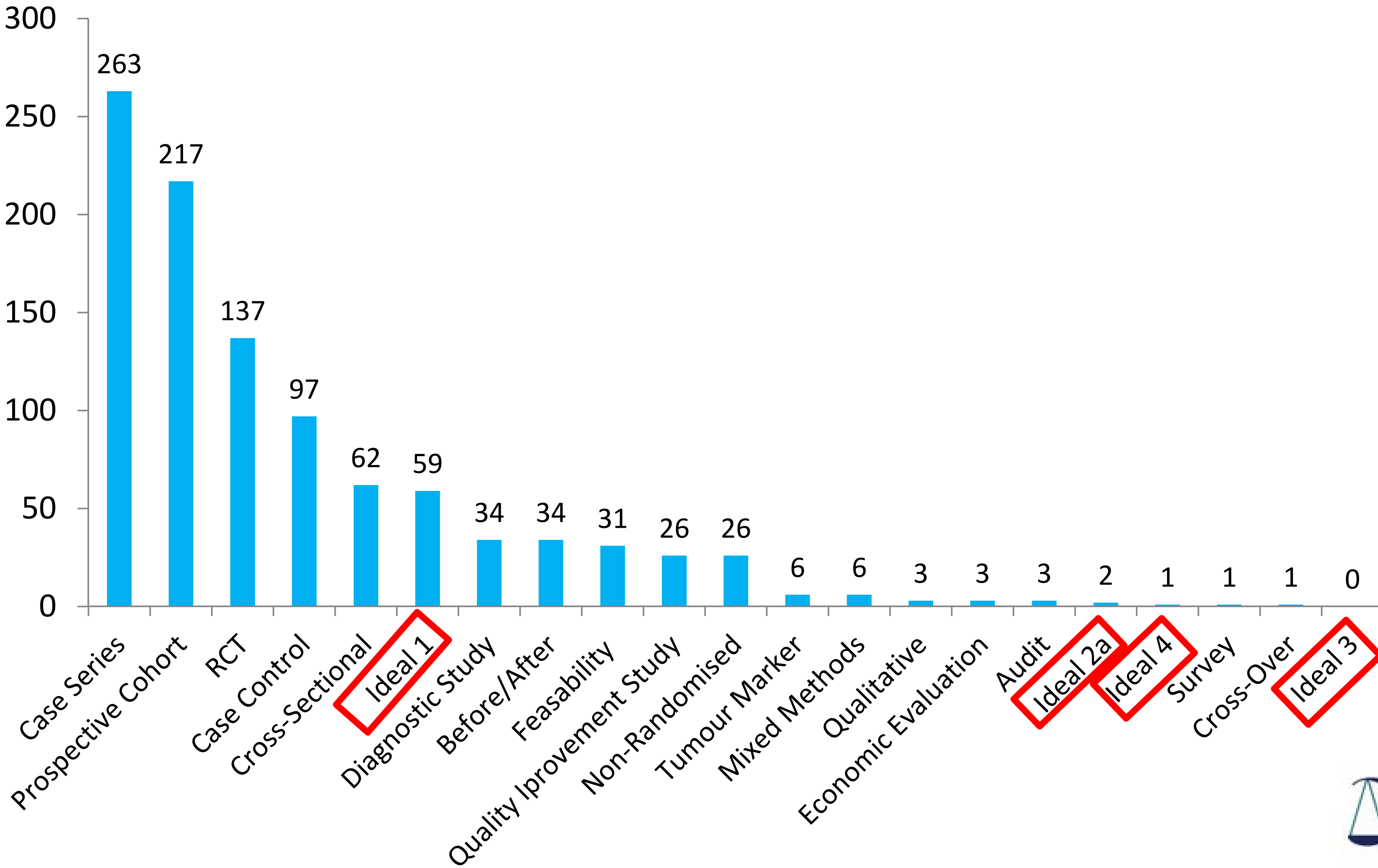
A mixed methods investigation of quality of life in patients with motor neurone disease (MND) and their carers - South Tees NHS Foundation Trust

The Efficacy of an 8-Week Concurrent Strength and Endurance Training Programme upon Hand Cycling Performance - Help for Heroes

Types of Registrations



Types of Registrations



First IDEAL Study to Register 03/2015

International Journal of Surgery 19 (2015) 104–111

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International Journal of Surgery

journal homepage: www.journal-surgery.net

ELSEVIER

Original research

The IDEAL prospective development study format for reporting surgical innovations. An illustrative case study of robotic oesophagectomy

CrossMark

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HIGHLIGHTS

- This paper demonstrates the use of the IDEAL Prospective Development Study format for presenting early work on surgical procedures.
- We show how transparency in reporting changes during development can allow others to benefit from the authors experience.
- The findings are of special interest to upper GI surgeons interested in using a robotic approach for oesophageal resection.

ARTICLE INFO

Article history:
Received 13 March 2015
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Keywords:
Oesophagectomy
Robotic
Methodology
Surgery
IDEAL

ABSTRACT

Background: The early development of innovative surgical procedures is usually reported as retrospective case series, wasting opportunities to provide useful information and introducing bias. We present a report of an innovative procedure in development, using the Prospective Development Study (PDS) format recommended by the IDEAL Collaboration.

Methods: We report the development of robotically assisted oesophagectomy by a two-surgeon team from the first robotic case onwards. Key outcomes (blood loss, robotic operating time, lymph node yield, length of stay and complications) are prospectively reported for each patient sequentially. Reasons for rejecting cases for robotic surgery are explained. All changes to technique or indication are highlighted, showing when they occurred and explaining why they were instituted.

Results: The first robotic oesophagectomy was attempted in December 2009. Subsequently 55 oeso-

Not a stage 2a study?

Registration Details

Research Registry Unique Identifying Number	researchregistry2456
Registration Date	April 28, 2017 07:49
Title of Research	Breast Cancer
Key Research Questions and Objectives	Breast cancer
Lay Summary (please do not just paste your abstract. Please summarise your research, written in a way the public can understand)	It is a breast cancer.
Study Type	IDEAL Stage 2a (Prospective Development Study)
Study Type Other (provide details)	It is a breast cancer.
Primary Investigator	Moh Moh
Other Investigator(s)	Ni Thet
Additional Investigators	Nilar
Contact Details for Queries	No,11, Ziwaka road, dagon.
Email	susumyaing1989@gmail.com
Participating Institution(s)	Cho Mar
Countries of Recruitment	Myanmar
Source(s) of Monetary or Material Support	Microscope
Health Condition(s) or Problem(s) Studied	Pathol
Patient Population	many
Intervention(s) - please describe in detail	it is a breast cancer testing.
Inclusion Criteria	Cancer
Exclusion Criteria	Breast
Control or Comparator(s)	brain cancer
Primary Outcome(s)	Good research
Key Secondary Outcomes	Knowledge sharing
Target Sample Size	large
Recruitment Status	Planning

Not a Stage 3 study

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Registration Details

Research Registry Unique Identifying Number	researchregistry2263
Registration Date	March 10, 2017 11:38
Title of Research	Ultrasonic system is an alternative technique for debridement in patients with diabetic foot ulcers? Authors:
Key Research Questions and Objectives	The authors present an experience on the safety and efficacy of a new tool for the surgical debridement of soft tissue for bone cutting in the diabetic foot in patients with diabetic foot ulcers (DFUs).
Lay Summary (please do not just paste your abstract. Please summarise your research, written in a way the public can understand)	An intervention of regenerative reconstructive surgery requires appropriate debridement with a demolitive treatment of infected tissue (soft-tissue and bone) and drainage of abscesses. Surgical debridement should cause only minimal damage to surrounding tissues. The preservation of viable tissue while removing necrotic tissue and slough allows wound healing to occur rapidly.
Study Type	IDEAL Stage 3 (assessment)
Study Type Other (provide details)	a retrospective study of 15 patients with diabetic foot ulcers

IDEAL Stage 4

Registration Details

Research Registry Unique Identifying Number	researchregistry1149
Registration Date	April 12, 2016 22:00
Title of Research	Register of urogynecological implants: development of an online platform for registration and outcome measurement according to the IDEAL framework
Key Research Questions and Objectives	-to report the effectiveness and the complications of medical devices and innovations -to identify longterm complications and risk factors for complications -to identify comparators for planned randomized trials -to assess Quality of Life and patient reported outcomes (PROMs) -to provide a framework for clinical studies, validation platform for questionnaires -to provide a platform for approval of medical products according to IDEAL stages
Lay Summary (please do not just paste your abstract. Please summarise your research, written in a way the public can understand)	Most aspects of implants for reconstruction of the pelvic floor for the treatment of urinary incontinence (UI) and pelvic organ prolapse (POP) are still under debate or poorly studied. Different tools and definitions of success in studies make the comparability of outcomes in this field of surgery difficult. Additionally, regulatory systems for medical device marketing approval lack adequate requirements for evidence of safety and efficacy. The aim of the present study is to implement a national surgical register to analyse the outcome after implant application and to improve the knowledge on indications, techniques and risk factors. The working group comprised of a national expert panel under auspices of German Society of Residents in Urology (GeSRU) and the Study Group for Urogynecology and Plastic Pelvic Floor Reconstruction (AGUB) of the German Society for Gynecology and Obstetrics with specific interest in urogynecology. The register includes three modules: • male incontinence • female incontinence • female pelvic organ prolapse The questionnaire design has been started during several meetings since January 2015. The definitions and criteria of evaluation were based on the classifications of International Continence Society (ICS), International Urogynecological Association (IUGA) and the current available literature. Firstly, a pilot study was started to evaluate the feasibility, time and cost effort. For these purpose initial 20 male and female patients, which underwent a new mesh device procedure for the treatment of POP and UI conditions were followed up retrospectively over 24 months. The evaluation of primary results has been completed. The results of IDEAL stage 0, 1 and 2a studies have been published previously. The next steps will include a consensus of the expert group on the relevant comparators und questions of the register. For this purpose a Delphi survey based on IDEAL recommendations is planned (adapted from Pennell et al., IJS 2016). Additionally to the expert group medical device industry, regulatory professionals, research funders, methodologists, statisticians, journal editors and IDEAL experts will be invited to participate in the survey. After the construction of the questionnaires of the modules it is planned to include new materials and device based techniques for the treatment of POP and SUI. The register can be classified as development stage of IDEAL framework (Stage 2a) and will help to improve innovative products and surgeries and identify risk factors and comparators for future randomized trials.
Study Type	IDEAL Stage 4 (long-term or Registry study)

Contact Details for Queries	Dimitri Barski, MD, FEBU (Fellow of European Board of Urology) Department of Urology, Lukas Hospital Neuss Preussenstrasse 84, 41464 Neuss, Germany Telephone: + 49-2131-8882401, Fax: + 49-2131-8882499 Mail: barskidimitri@gmail.com
Email	
Participating Institution(s)	1 Department of Urology, Lukas Hospital Neuss, Germany 2 University Hospital for Urology, Klinikum Oldenburg, School of Medicine and Health Sciences, Carl von Ossietzky University Oldenburg, Germany 3 Department of Urology, HELIOS Hospital, Bad Saarow, Germany 4 Department of Gynecology, University Hospital Würzburg, Germany 5 Department of Urology, St.-Antonius Hospital Eschweiler, Germany 6 Department of Urology, University Hospital Hamburg Eppendorf, Germany 7 Department of Urology, University Hospital Münster, Germany 8 Department of Urology, University Hospital Greifswald, Germany 9 Department of Urology, University Hospital Halle (Saale), Germany 10 Department of Urology, LMU University Hospital Munich, Germany 11 Department of Neuro-Urology, University Hospital Bonn, Germany 12 Department of Urology, Ingolstadt, Germany 13 Surgical Department, University Hospital of the RWTH Aachen, Germany 14 Institute of Experimental Surgery, University of Szeged, Hungary 15 Department of Gynecology, Klinikum Bielefeld, Germany 16 Department of Gynecology, HELIOS hospital, Erfurt, GErmany 17 Institute for Mathematics and Computer Science, University of Würzburg, Germany
Countries of Recruitment	Germany
Source(s) of Monetary or Material Support	National strategy process "Innovations in medical technology" supported by the Federal Institute for Drugs and Medical Devices, the Federal Ministry of Economics and Technology, the Federal Ministry of Education and Research and the Federal Ministry of Health.
Health Condition(s) or Problem(s) Studied	Urinary incontinence and pelvic organ prolapse
Patient Population	Adult male and female patients older than 18 years with the indication for implant assisted treatment of urinary incontinence (UI) and/or pelvic organ prolapse (POP).
Intervention(s) - please describe in detail	Intervention will be defined by the procedure (f.e. anterior vaginal repair) and device (f.e. name, manufacturer and modifications of the mesh) used

Conclusion – a good start…

- The most comprehensive range of study types of any research registry + free + instant registration
- Global and growing 2,410 registrations, 80 countries.
- >8m patients registered via studies which otherwise may not have been.
- Quality Indicators – 44% -> 100% (first 500)
- RR2000 study underway
- IDEAL studies are <3% of the database

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- International Advisory Board

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Collaboration

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