James Lind 1753

Konservativ RCT innen spesialisthelsetjenesten – hvilke konsekvenser har resultatene?

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Spesialisthelsetjenesten (efficacy)

- Presis diagnostikk, selekterte pasienter
- Sykdomsspesifikke utfallsmål

Primær helsetjenesten (effectiveness)

- Ikke selekterte pasienter
- Selv-rapporterte utfallsmål

The NEW ENGLAND JOURNAL of MEDICINE

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Intracoronary Injection of Mononuclear Bone Marrow Cells in Acute Myocardial Infarction

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RESULTS

Of the 50 patients assigned to treatment with mononuclear BMC, 47 underwent intracoronary injection of the cells at a median of 6 days after myocardial infarction. There were 50 patients in the control group. The mean (±SD) change in LVEF, measured with the use of SPECT, between baseline and 6 months after infarction for all patients was 7.6±10.4 percentage points. The effect of BMC treatment on the change in LVEF was an increase of 0.6 percentage point (95% confidence interval [CI], −3.4 to 4.6; P=0.77) on SPECT, an increase of 0.6 percentage point (95% CI, −2.6 to 3.8; P=0.70) on echocardiography, and a decrease of 3.0 percentage points (95% CI, 0.1 to −6.1; P=0.054) on MRI. The two groups did not differ significantly in changes in left ventricular end-diastolic volume or infarct size and had similar rates of adverse events.

CONCLUSIONS

With the methods used, we found no effects of intracoronary injection of autologous mononuclear BMC on global left ventricular function. (ClinicalTrials.gov number, NCT00199823.)

EFFECT OF DIETARY SUPPLEMENTATION WITH VERY-LONG-CHAIN n−3 FATTY ACIDS IN PATIENTS WITH PSORIASIS

ELISABETH SØYLAND, M.D., JÜRGEN FUNK, M.D., GEORG RAJKA, M.D., PH.D., MORTEN SANDBERG, M.D., PER THUNE, M.D., PH.D., LISBETH RUSTAD, M.D., SVEIN HELLAND, M.D., PH.D., KJELL MIDDELFART, M.D., SOLVEIG ODU, M.D., EDVARD S. FALK, M.D., PH.D., KARI SOLVOLL, M.SC., GUNN-ELIN AA. BJØRNEBOE, M.D., PH.D., AND CHRISTIAN A. DREVON, M.D., PH.D.

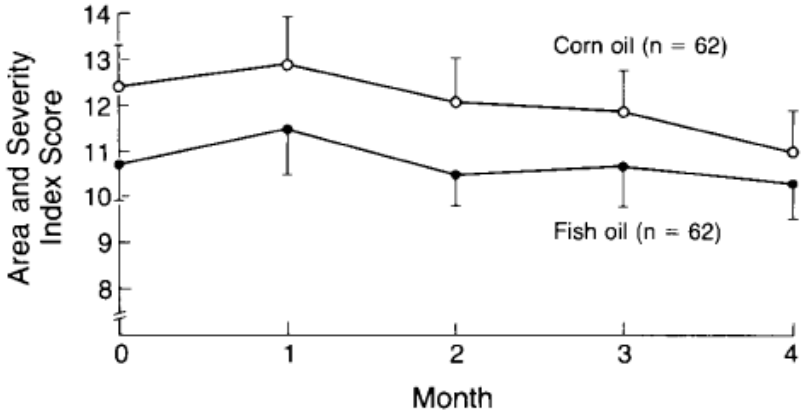
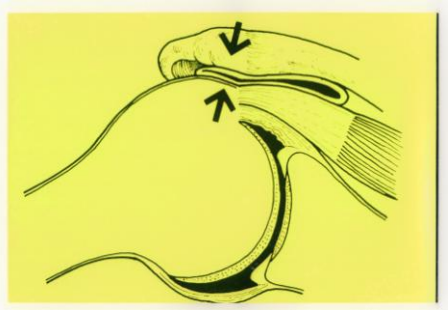


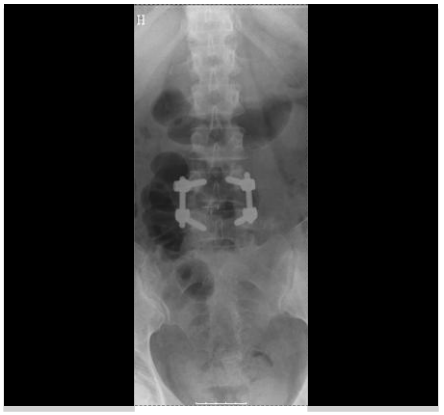
Figure 1. Mean (±SE) Effect of Dietary Supplementation with Fish Oil or Corn Oil on Psoriasis Area and Severity Index Scores.

Sammenliknende studier av operativ og ikke-operativ behandling



- Alle inkluderte pasienter må være kandidater for operasjon
- Den ikke-operative behandlingen må fremstå som et likeverdig alternativ
- Operasjon har den største placeboeffekt
- Den klinisk signifikante behandlingseffekten må være minst like stor som målefeilen hos en enkelt pasient

Sammenliknende studier av operativ og ikke-operativ behandling



- Det kan diskuteres om en skal sammenlikne den rutinemessige behandling eller etterstrebe å optimalisere begge behandlingsalternativer
- Alle pasienter har rett til å trekke seg etter Helsinkideklarasjonen, men det er god grunn til å prøve og unngå at det skjer
- Randomiseringen og evalueringen må være blindet

BMJ 1993;307:899-903

Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage II impingement syndrome)

Jens Ivar Brox, Peer H Staff, Anne Elisabeth Ljunggren, John Ivar Brevik

Abstract

Objective—To compare the effectiveness of arthroscopic surgery, a supervised exercise regimen, and placebo soft laser treatment in patients with rotator cuff disease (stage II impingement syndrome).

Design—Randomised clinical trial.

Setting—Hospital departments of orthopaedics and of physical medicine and rehabilitation.

Patients—125 patients aged 18-66 who had had rotator cuff disease for at least three months and whose condition was resistant to treatment.

Interventions—Arthroscopic subacromial decompression performed by two experienced surgeons; exercise regimen over three to six months supervised by one experienced physiotherapist; or 12 sessions of detuned soft laser treatment over six weeks.

Main outcome measures—Change in the overall Neer shoulder score (pain during previous week and blinded evaluation of function and range of movement by one clinician) after six months.

Results—No differences were found between the three groups in duration of sick leave and daily intake of analgesics. After six months the difference in improvement in overall Neer score between surgery and supervised exercises was 4·0 (95% confidence interval −2 to 11) and 2·0 (−1·4 to 5·4) after adjustment for sex. The condition improved significantly compared with placebo in both groups given the active treatments. Treatment costs were higher for those given surgery (£720 *v* £390).

Conclusions—Surgery or a supervised exercise regimen significantly, and equally, improved rotator cuff disease compared with placebo.

	Arthroscopic surgery	Supervised exercises	Placebo laser
		Pain	
On activity:			
Baseline	7·0	7·0	7·0
3 Months	3·0	4·0	6·0
6 Months	3·0	3·0	6·0

EXTENDED REPORT

Exercises versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up

J P Haahr, S Østergaard, J Dalsgaard, K Norup, P Frost, S Lausen, E A Holm, J H Andersen

Ann Rheum Dis 2005;**64**:760–764. doi: 10.1136/ard.2004.021188

Conclusions: Surgical treatment of rotator cuff syndrome with subacromial impingement was not superior to physiotherapy with training. Further studies are needed to qualify treatment choice decisions, and it is recommended that samples are stratified according to disability level.

THE JOURNAL OF BONE & JOINT SURGERY (BR)

Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome?

A TWO-YEAR RANDOMISED CONTROLLED TRIAL

S. Ketola

J Bone Joint Surg [Br] 2009;91-B:1326-34.

Arthroscopic acromioplasty provides no clinically important effects over a structured and supervised exercise programme alone in terms of subjective outcome or cost-effectiveness when measured at 24 months. Structured exercise treatment should be the basis for treatment of shoulder impingement syndrome, with operative treatment offered judiciously until its true merit is proven.

The Rising Incidence of Acromioplasty

By Mark A. Vitale, MD, MPH, Raymond R. Arons, MPH, DrPH, Shepard Hurwitz, MD, Christopher S. Ahmad, MD, and William N. Levine, MD

Investigation performed at New York-Presbyterian/Columbia University Medical Center, New York, NY

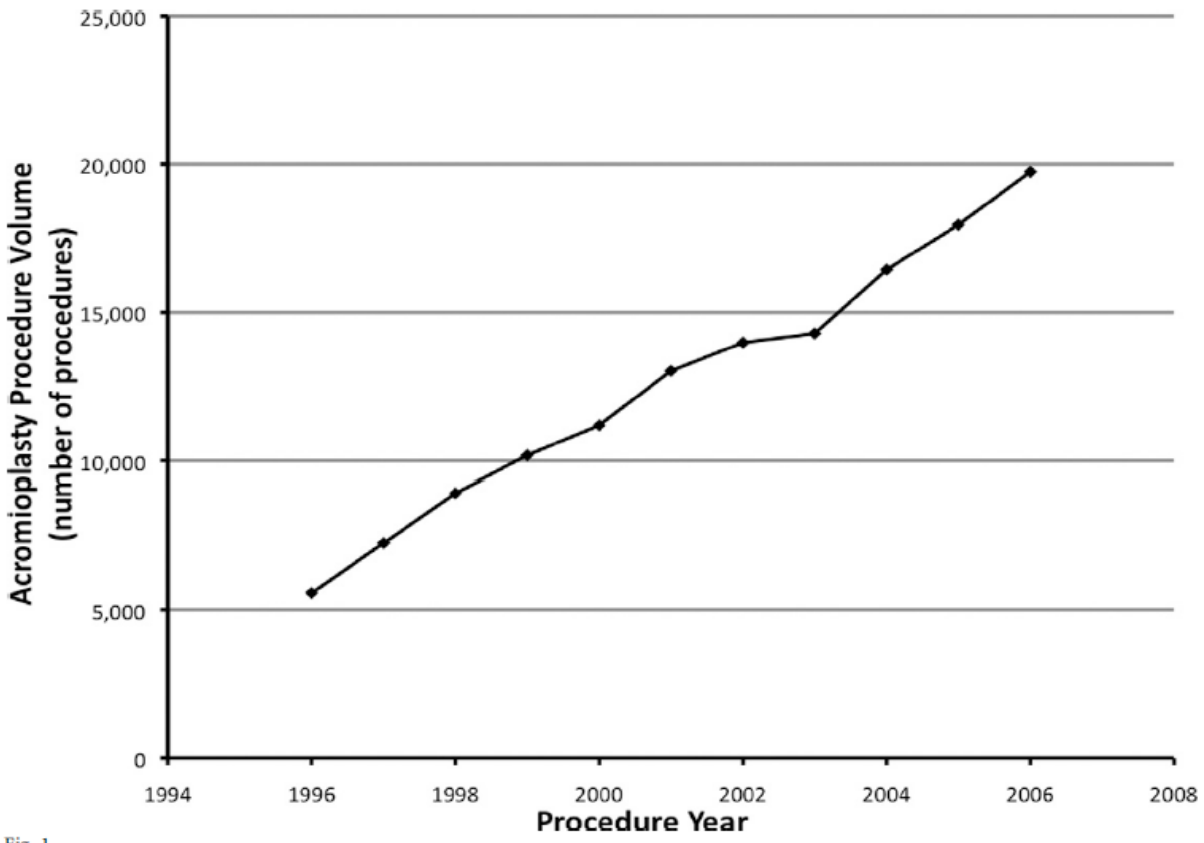


Fig. 1

Line graph showing the volume of acromioplasty procedures by year in New York State.

Randomiserte skulderstudier
– faglig seminar og ski fra Skarsnuten i Hemsedal 2007-

BMJ

RESEARCH

Subacromial ultrasound guided or systemic steroid injection for rotator cuff disease: randomised double blind study

Ole M Ekeberg, research fellow ,[1] Erik Bautz-Holter, professor ,[1] Einar K Tveitå, research fellow ,[1] Niels G Juel, consultant physician ,[1] Synnøve Kvalheim, consultant physician ,[1] Jens I Brox, consultant physician[2,3]

BMJ

RESEARCH

Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study

Kaia Engebretsen, physiotherapist,[1,2] Margreth Grotle, research leader,[2,3] Erik Bautz-Holter, professor,[1,2] Leiv Sandvik, professor,[4] Niels G Juel, MD consultant,[1,2] Ole Marius Ekeberg, Research fellow,[1,2] Jens Ivar Brox, MD consultant[2,5]

Skare *et al. BMC Musculoskeletal Disorders* 2010, **11**:228
http://www.biomedcentral.com/1471-2474/11/228

BMC Musculoskeletal Disorders

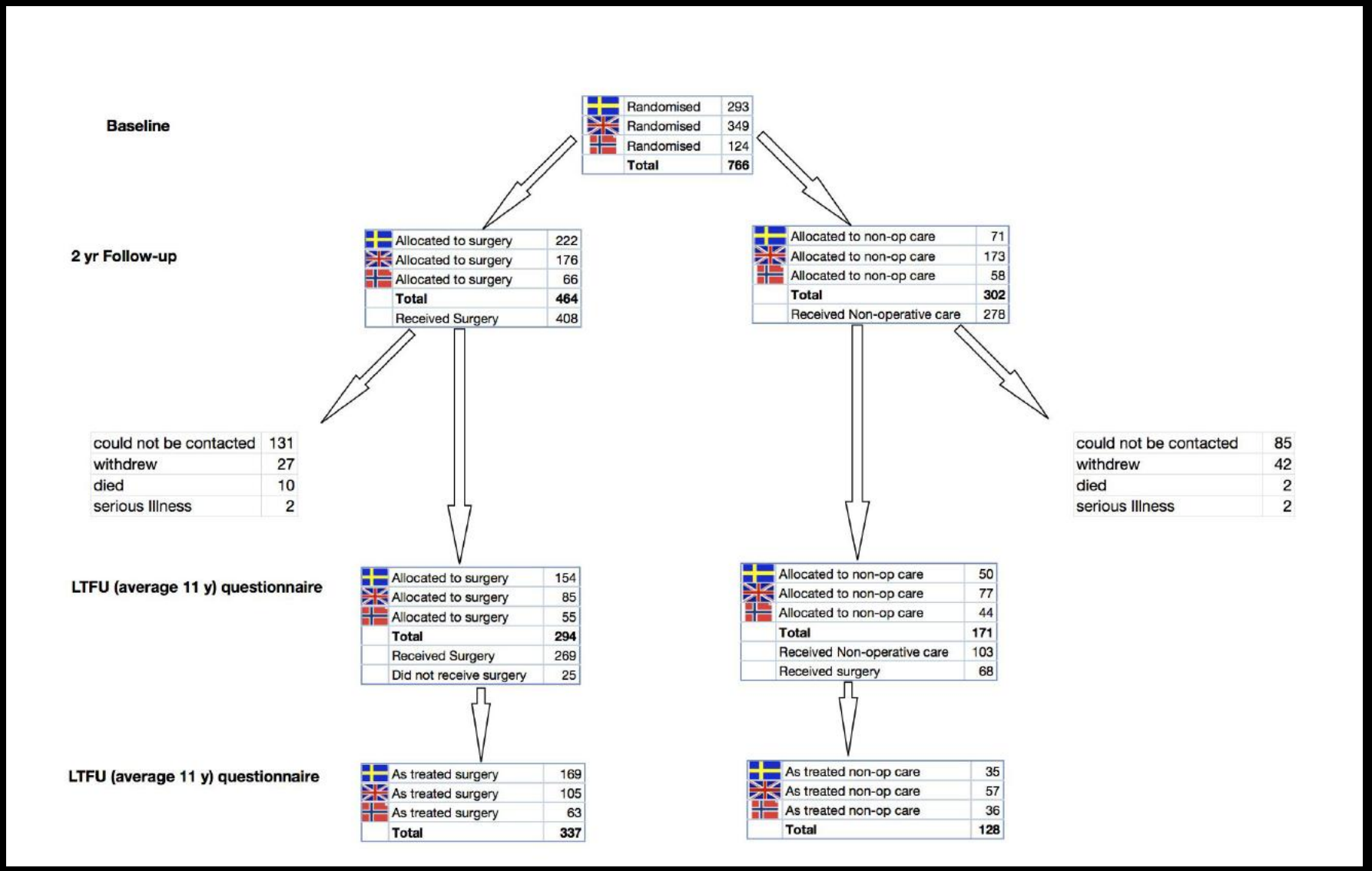
STUDY PROTOCOL Open Access

Efficacy of labral repair, biceps tenodesis, and diagnostic arthroscopy for SLAP Lesions of the shoulder: a randomised controlled trial

Øystein Skare[1*], Cecilie Piene Schrøder[1], Olav Reikerås[2], Petter Mowinckel[3], Jens Ivar Brox[2]

A comparison of spinal fusion and non-surgical treatment in patients with chronic low back pain: an average 11-year follow-up of four randomized controlled trials from Norway, Sweden and UK

Anne F Mannion PhD[1], Jens-Ivar Brox MD PhD[2],Olle Hägg MD PhD[3], Peter Fritzell MD PhD[4], Jeremy Fairbank MD FRCS[5]

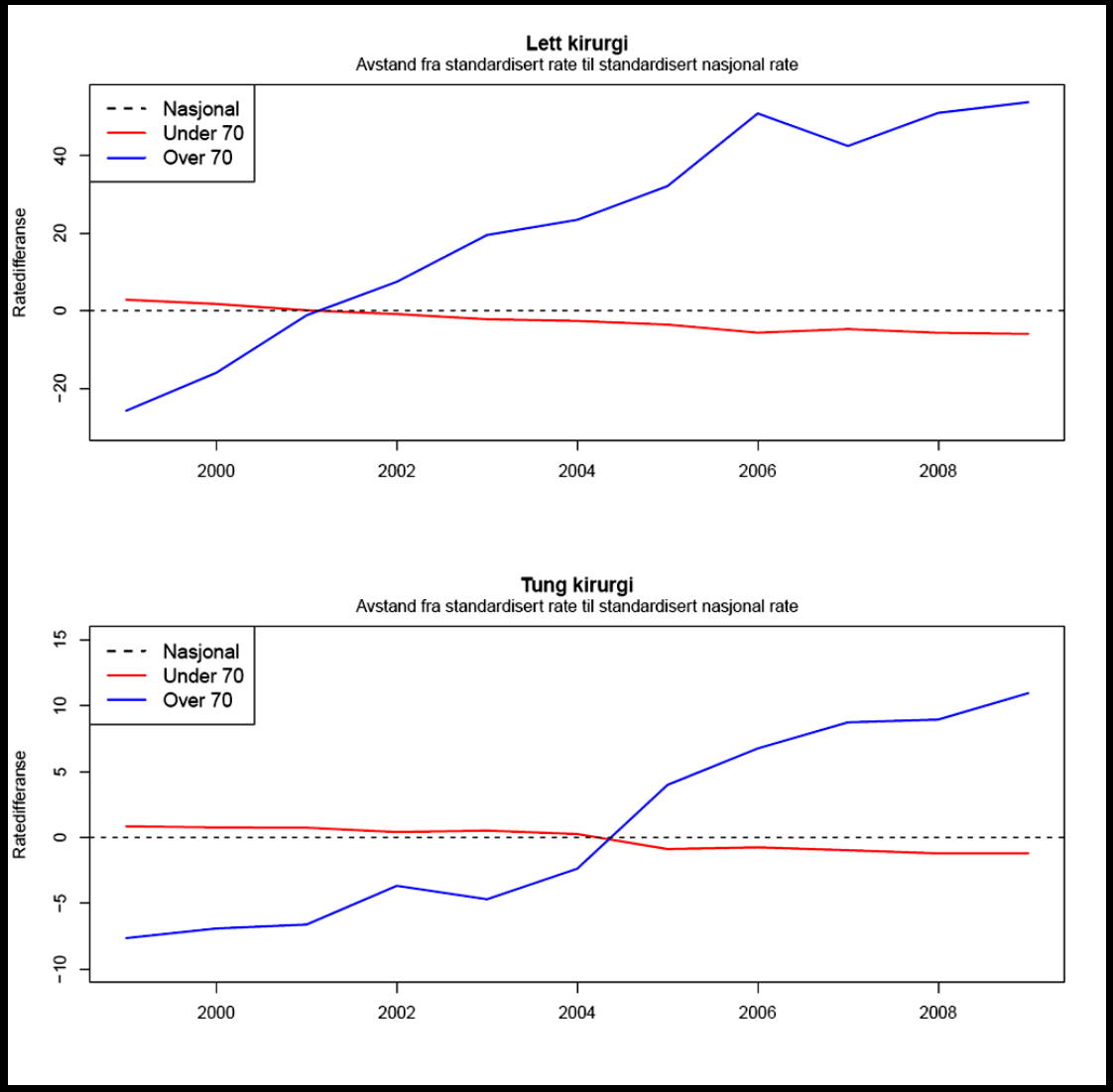

Baseline
Randomised 293
Randomised 349
Randomised 124
Total 766
2 yr Follow-up
Allocated to surgery 222
Allocated to surgery 176
Allocated to surgery 66
Total 464
Received Surgery 408
Allocated to non-op care 71
Allocated to non-op care 173
Allocated to non-op care 58
Total 302
Received Non-operative care 278
could not be contacted 131
withdrew 27
died 10
serious Illness 2
could not be contacted 85
withdrew 42
died 2
serious Illness 2
LTFU (average 11 y) questionnaire
Allocated to surgery 154
Allocated to surgery 85
Allocated to surgery 55
Total 294
Received Surgery 269
Did not receive surgery 25
Allocated to non-op care 50
Allocated to non-op care 77
Allocated to non-op care 44
Total 171
Received Non-operative care 103
Received surgery 68
LTFU (average 11 y) questionnaire
As treated surgery 169
As treated surgery 105
As treated surgery 63
Total 337
As treated non-op care 35
As treated non-op care 57
As treated non-op care 36
Total 128

Results

- The mean adjusted treatment effect of non-operative treatment was -1.1 points (95% confidence interval -4.7 to 2.5) for ITT and 0.6 (-3.4 to 4.6) as treated.
- There were no treatment effects for the secondary outcomes.

Back surgery Norway 1999 - 2009

n= 53.347 (NORspine and NPR)



Sammenfatning

- Gode randomiserte studier gir bedre kunnskap om best behandling
- Gode randomiserte studier bedrer forskningskvaliteten på en avdeling
- De beste randomiserte studiene i spesialisthelsetjenesten kan publiseres i de beste tidsskriftene

Sammenfatning

- Randomiserte studier er idealet for å vurdere kausal sammenheng mellom behandling og resultat
- Randomiserte studier i spesialist- og primærhelsetjenesten trenger ikke være forskjellige
- Multisenterstudier anbefales når det ikke er mulig å gjennomføre studien på et behandlingssted
- Forvent ikke randomiserte studier raskt endrer klinisk praksis