AKADEMISKA SJUKHUSET

UPPSALA UNIVERSITET

Lung UltraSound as Alternative to Radiography after Thoracic Surgery (LUS-ART): a randomized controlled trial

Interim analysis summary

Date: 08-22-2024

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Clinicaltrials.gov Identifier: NCT06261411

Swedish Ethical Review Authority Identifier: 2023-06510-01

Hospital/university trial Identifier: FOU2024-00038

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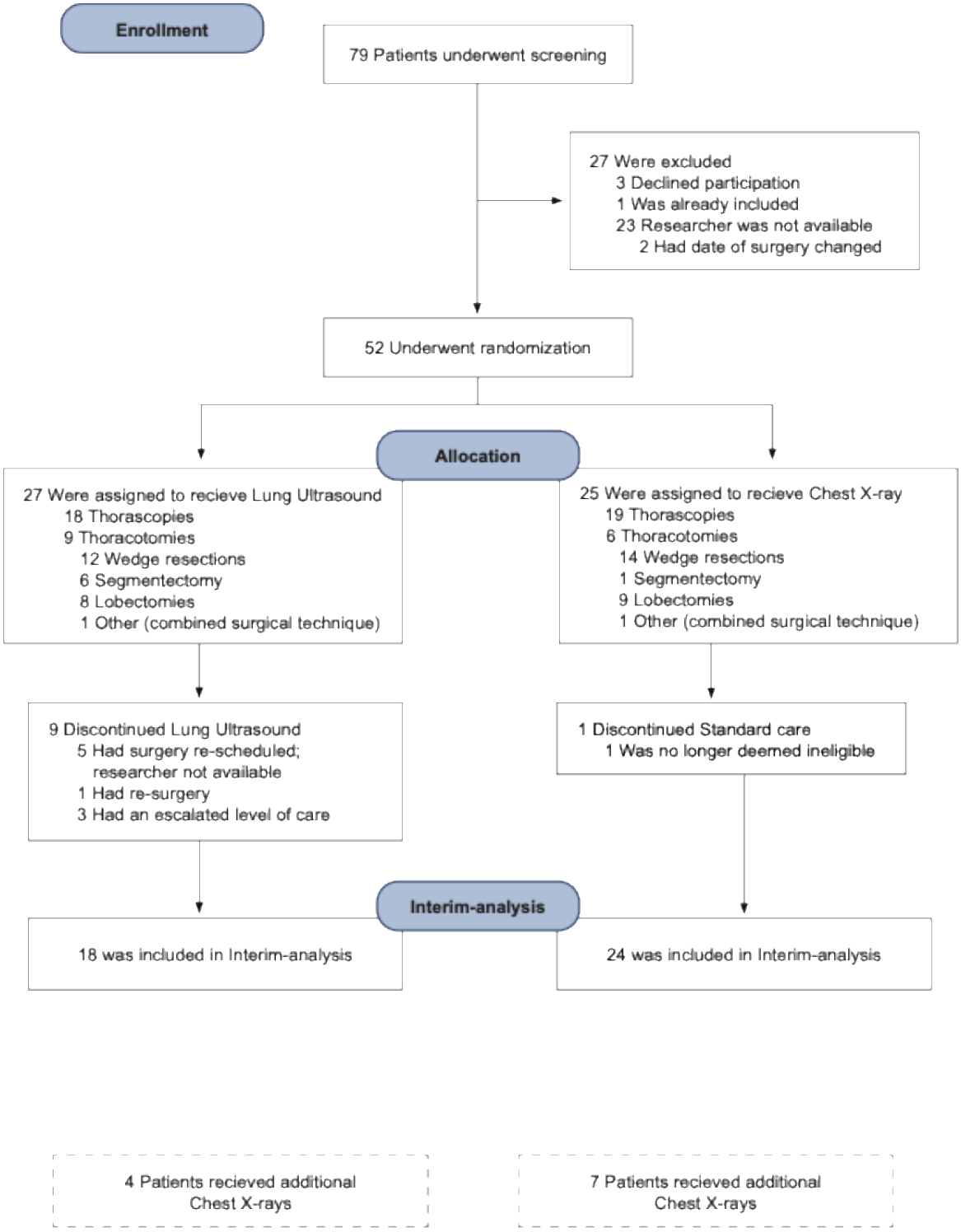
Enrollment
79 Patients underwent screening
27 Were excluded
3 Declined participation
1 Was already included
23 Researcher was not available
2 Had date of surgery changed
52 Underwent randomization
Allocation
27 Were assigned to recieve Lung Ultrasound
18 Thorascopies
9 Thoracotomies
12 Wedge resections
6 Segmentectomy
8 Lobectomies
1 Other (combined surgical technique)
25 Were assigned to recieve Chest X-ray
19 Thorascopies
6 Thoracotomies
14 Wedge resections
1 Segmentectomy
9 Lobectomies
1 Other (combined surgical technique)
9 Discontinued Lung Ultrasound
5 Had surgery re-scheduled; researcher not available
1 Had re-surgery
3 Had an escalated level of care
1 Discontinued Standard care
1 Was no longer deemed ineligible
Interim-analysis
18 was included in Interim-analysis
24 was included in Interim-analysis
4 Patients recieved additional Chest X-rays
7 Patients recieved additional Chest X-rays

Patient and perioperative characteristics	**LUS (n=18)**	**CXR (n=24)**	
Sex (no females, %)	10 (55)	16 (66)	0.4631
Age (yrs)	66 (58 to 73)	72 (67 to 76)	0.1167
BMI (kg m^{-2})	27 (26 to 29)	26 (24 to 25)	0.2443
Type of surgery			ns
Wedge resection	8 (44)	14 (58)	
Segmentectomy	5 (28)	1 (4)	
Lobectomy	5 (28)	8 (33)	
Other	0	1 (4)	
Thoracoscopy/Thoracotomy	14/4 (78/22)	18/6 (75/25)	0.9991
Conversion to open surgery	0	2 (8)	0.4983
History of smoking*			0.8277
Non-smoker	5 (31)	6 (26)	
Previous smoker	9 (56)	12 (52)	
Active smoker	2 (13)	5 (22)	
Preoperative lungfunction (FEV1, L)**	2.6 (2.1 to 3.0)	2.1 (1.9 to 2.4)	0.0629
Previous lung surgery	0 (0)	2 (8)	0.4983
Comorbidities			ns
Asthma	2 (11)	0	
COPD	3 (17)	4 (17)	
Hypertension	9 (50)	12 (50)	
Cong heart failure	2 (11)	1 (4)	
Cancer	12 (67)	11 (45)	
Diabetes mellitus	2 (11)	3 (13)	
Renal impairment	1 (6)	0	
Surgical bleeding (ml), median (range)	0 (0-50)	0 (0-100)	0.762
Intraoperative ventilation settings§ (no,%)			
PRVC/VC/PC	17/1/0	17/7/0	0.1257
FiO2	69 (63 to 74)	67.5 (73 to 72)	0.9563
PEEP (cm H_2O)	5.2 (5.2 to 5.8)	5.5 (5.1 to 5.9)	0.4782
Ppeak (cm H_2O)	17 (16 to 19)	18 (17 to 20)	0.4898

*Categorical data is presented as N (%) and continuous data as mean (95% CI) or otherwise specified. *2 unknown in CXR arm and 1 unknown in LUS arm. **1 missing value in CXR arm and 2 missing values in LUS arm. § Ventilation settings at the end of surgery on double lung ventilation, PRVC; pressure regulated volume controlled mode: VC; volume controlled mode: PC; pressure controlled mode*

Statistical analysis: Independent t-test with Welch's correction or Mann-Whitney U-test for continuous samples. Chi-square or Fisher exact test for categorical variables.

Outcomes	**LUS (N=18)**	**CXR (N=24)**	
No. x-rays performed per pt.	1 (1 - 5)	2 (1 - 6)	0.0580
Additional x-rays§ per pt. No. (%) of pts receiving additional x-rays	0 (0 - 4) 4 (22%)	0 (0 - 4) 8 (33%)	0.4846 RR 0.80 (0.49 to 1.47)
Time to drain removal (min)	320 (88-7709)	315 (153-9930)	0.9150
Late drain removal, >1 day (no.%)	4 (22%)	5 (21%)	0.9999 RR 1.0 (0.60 to 2.3)
Adverse events/PPC, no. %	7 (39%)	6 (25%)	0.9284 RR 1.35 (0.76 to 2.80)
Length of stay (days)	4 (2-8)	4 (3-9)	0.2311

Data presented as median (range) or otherwise specified. § No of CXR performed in addition to protocol. Relative risk (95%CI) of receiving CXR in addition to protocol (1 CXR for all patients in LUS arm and 2 for lobectomies/segmentectomies and 1 for wedge resections in CXR arm). Early X-ray 4 pts in LUS arm and 6 pts in CXR arm.

Statistical analysis: Independent sample median test, Pearson chi square with Yates continuity correction, Mann-Whitney U test

INTEROBSERVER AGREEMENT

Interobserver reliability for the LUS investigations, using intraclass correlation (ICC) for consistency(C) and absolute agreement (A), was evaluated for the following assessments:
Aeration score ICC-C 0.865/0.852 ICC-A 0.860/0.834 (dx/sin)
Pneumothorax-ICC-C 0.883/0.809 ICC-A 0.885/0.809 (dx/sin)
Pleural effusion ICC-C 0.887/0.769 ICC-A 0.882/0.776 (dx/sin)
(LUS investigation no 1 in all cases)

ICC: (>0.75 good >0.8 very good >0.9 excellent)

SUMMARY:

- 42 patients were included in this interim analysis, 18 in the LUS/intervention arm and 24 in the CXR arm. The trial is set to include 110 patients.
- More patients in the LUS arm were excluded due to re-scheduling of surgery, this can pose a problem as the LUS/intervention arm is more logistically demanding.

- There were no differences in baseline characteristics between patients allocated to the LUS/intervention and the CXR arm.
- There was a tendency towards lower total number of chest x-rays in the LUS/intervention group. However, this difference was smaller when looking at additional x-rays.
- There were no signals of delayed drain removal, increased number of adverse events, increased length of stay or increased number of additional x rays in the LUS/intervention arm.
- Interobserver consistency and agreement for LUS was generally very good for key assessments.