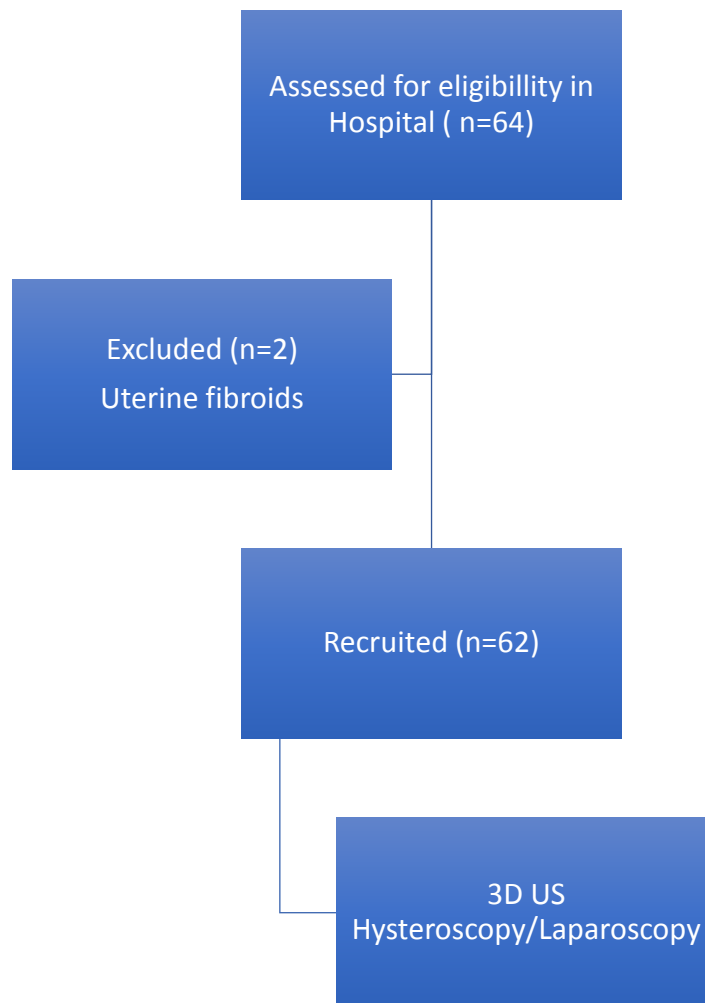


## Participant Flow:



### Baseline Characteristics:

Table 1: Demographic and clinical characteristics of the patients

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Age (years) ; Mean±SD (min-max)	31.7±5.6 (13-42)
Infertility / Recurrent abortions; n(%)	33 / 62 (53.2%)
Number of pregnancies (0 / 1 / 2 / 3+) ; n(%)	26(42%) / 13(21%) / 18(29%) / 5(8%)
Number of deliveries (0 / 1 / 2) ; n(%)	44 ( 71%) / 11 ( 17%) / 7 ( 11.3%)

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## Outcome Measures:

**Table 2** : Concordance between 3D US and HL

		H/L						Total	
		U0	U1	U2	U3	U4	U5		
3D ULTRASOUND	U0	N	<b>1</b>	0	0	0	0	0	1
		%	<b>1.6%</b>	,0%	,0%	,0%	,0%	,0%	1.6%
	U1	N	0	<b>3</b>	0	0	0	0	3
		%	,0%	<b>4.8%</b>	,0%	,0%	,0%	,0%	4.8%
	U2	N	<b>1</b>	0	<b>49</b>	0	0	0	50
		%	<b>1.6%</b>	,0%	<b>78.9%</b>	,0%	,0%	,0%	80.5%
	U3	N	0	0	0	<b>3</b>	0	0	3
		%	,0%	,0%	,0%	<b>4.8%</b>	,0%	,0%	4.8%
	U4	N	0	0	0	0	<b>4</b>	0	4
		%	,0%	,0%	,0%	,0%	<b>6.5%</b>	,0%	6.5%
	U5	N	0	0	0	0	0	<b>1</b>	1
		%	,0%	,0%	,0%	,0%	,0%	<b>1.6%</b>	1.6%
	Total	N	2	3	49	3	4	1	62
		%	3.2%	4.8%	78.9%	4.8%	6.5%	1.6%	100.0%

Exact concordance (Kappa index 0.945) between 3DUS and H &L about the type and classification of uterine anomaly was verified in 61/62 cases (Table 6). Only in one case there was discordance between 3DUS and endoscopy: a case with normal uterus was diagnosed with the 3DUS as a partial septum

Table 3: Diagnostic accuracy of 3DUS in the evaluation of uterine anomalies in the study population compared to the findings of Hysteroscopy/Laparoscopy.

	Sensitivity	Specificity	PPV	NPV	Kappa value
U0	0.500(1/2) (0.03-0.97)	1.00(60/60) (0.92-1.00)	1.00(1/1) (0.05-1.00)	0.984(60/61) (0.90-1.00)	0,659 (0,04-1,00)
U1	1.00 (3/3) (0.31-0.99)	1.00 (59/59) (0.92-1.00)	1.00 (3/3) (0.31-1.00)	1.00 (59/59) (0.92-1.00)	1,00 (1,00-1,00)
U2	1.00(49/49) (0.91-1.00)	0.923(12/13) (0.62-1.00)	0.980(49/50) (0.88-1.00)	1.00(12/12) (0.70-1.00)	0,950 (0,85-1,00)
U3	1.00(3/3) (0.31-1.00)	1.00(59/59) (0.92-1.00)	1.00(3/3) (0.31-1.00)	1.00(59/59) (0.92-1.00)	1,00 (1,00-1,00)
U4	1.00(4/4) (0.40-1.00)	1.00(58/58) (0.92-1.00)	1.00(4/4) (0.40-1.00)	1.00(58/58) (0.92-1.00)	1,00 (1,00-1,00)
U5	1.00(1/1) (0.05-1.00)	1.00(61/61) (0.92-1.00)	1.00(1/1) (0.05-1.00)	1.00(61/61) (0.92-1.00)	1,00 (1,00-1,00)

For the diagnosis of septate uteri, which was the most common anomaly, the sensitivity of 3D US was 100%, the specificity was 92.3%, the PPV was 98% and the NPV was 100%, with kappa index 0.950. For bicorporeal, dysmorphic uterus, hemi-uteri or unicorporeal and aplastic uterus the sensitivity, specificity, PPV and NPV were all 100% with K=1.00. Overall, 3D US showed perfect diagnostic accuracy (Kappa index = 0.945 ) in the detection of congenital uterine anomalies

**Adverse Events:**

There were no adverse events associated with this trial.