Participant Demographic Information

A total of thirty (30) participants were successfully recruited into the study. The details of the study were explained to their parents/guardians and their wards were included in the study upon receipt of their informed consent. These were divided into three (3) groups with each comprising ten (10) participants. All 30 participants received the designated treatment per the group assigned. Five (5) participants were excluded prior to analysis as their sedation failed.

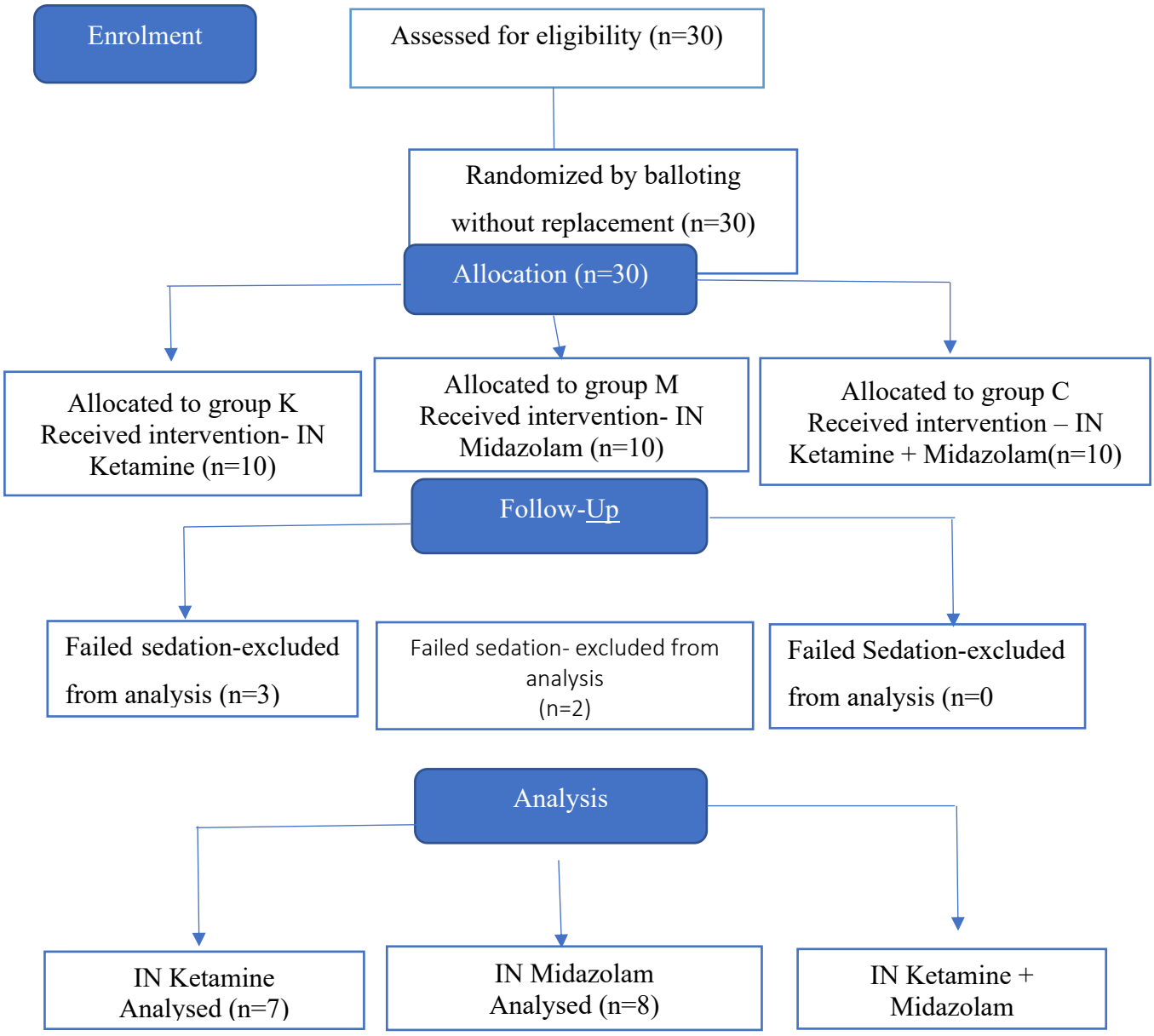

Figure 4. 1: Consort Flow Diagram

The oldest participant was 2.5yrs old while the youngest was a 1week old neonate. The mean age of the participants was 1.08 years. Three (3) out of every 5 (i.e., 60%) participants were females; males 40%. There was no purposive selection of participants based on sex. Majority of the participants (72%) had head CT scan done as their imaging procedure.

The rest of the demographic characteristics are shown in tables 4.1 and 4.2.

Table 4. 1: Demographic characteristics of all analysed participants

	Range		
	Minimum	Maximum	Mean (SD)
Age (years)	0.02	2.50	1.08 (0.79)
Weight (kilograms)	3.00	10.00	7.57 (2.68)
Height (meters)	0.45	0.91	0.71 (0.15)
Body Mass Index (kg/m^2)	10.70	18.90	14.78 (2.31)

SD= Standard Deviation

Table 4. 2: Socio-demographic characteristics of all analysed participants

	Frequency (n)	Percentage (%)
Sex		
Male	10	40.0
Female	15	60.0
Type of imaging		
Head	18	72.0
Chest	4	16.0
Abdomen	2	8.0
Kidney-Ureters-Bladder (KUB)	1	4.0
ASA		
I	11	44.0
II	14	56.0

4.2 Demographic characteristics among the study groups

From table 4.3, there was no statistically significant difference between the three study groups with respect to age, weight, height and BMI. Therefore, the study groups were comparable.

Table 4. 3: Distribution of social-demographic characteristics among the various groups

	Group	N	Range	Mean (SD)	F test	p-value
Age (years)	K	7	0.25-2.50	1.42 (0.82)	1.416	0.264
	M	8	0.02-2.00	0.74 (0.83)		
	C	10	0.04-2.00	1.11 (0.70)		
Weight(kilograms)	K	7	4.00-12.00	8.47 (2.66)	1.323	0.287
	M	8	3.00-10.00	6.36 (2.87)		
	C	10	3.90-10.00	7.90 (2.46)		
Height (meters)	K	7	0.61-0.91	0.76 (0.11)	1.396	0.269
	M	8	0.45-0.86	0.64 (0.17)		
	C	10	0.46-0.85	0.72 (0.14)		
BMI (kg/m^2)	K	7	10.70-17.80	14.26 (2.63)	0.238	0.790
	M	8	11.90-18.50	15.01 (2.37)		
	C	10	11.80-18.90	15.01 (2.37)		

SD= Standard Deviation, K= Ketamine, M= Midazolam, C= Ketamine and Midazolam, BMI= Body Mass Index

4.3 Gender Distribution of participants among the study groups

There was no statistically significant difference in gender between participants in each of the 3 study groups (*p*-value of 0.872). Thus, the sex distribution in each group is comparable.

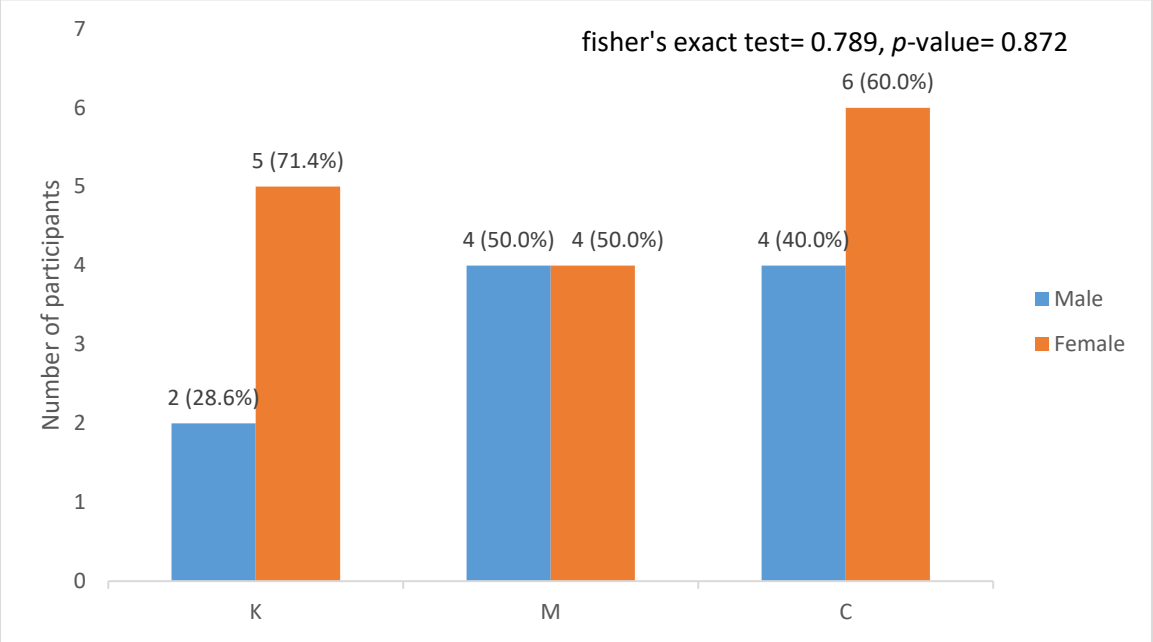

Figure 4. 2: Gender Distribution of participants among the study groups

4.4 ASA distribution of participants among the group

There was a significant difference in the proportions of ASA class distribution between study groups K, M and C, *p*-value=0.033 (Figure 4.3)

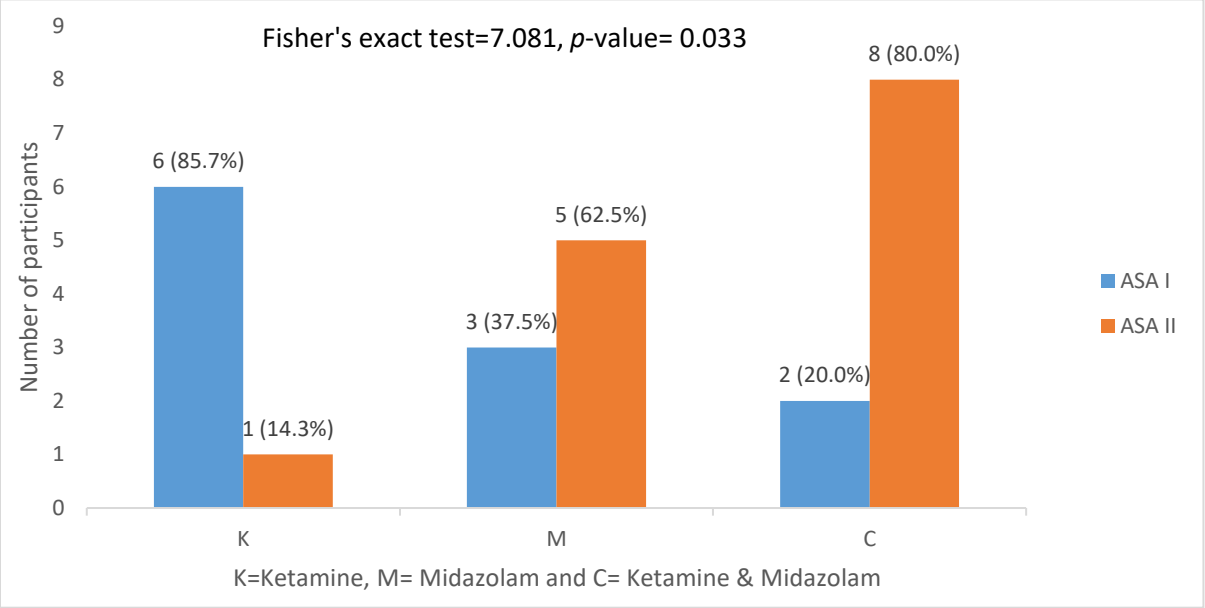

Figure 4. 3: ASA distribution of participants among the group

General characteristics of the study participants

A total of thirty (30) participants were successfully recruited into the study. These were divided into 3 groups with each comprising 10 participants: K (intranasal ketamine group), M (intranasal midazolam group) and C (combination of intranasal ketamine and midazolam group). Five (5) participants were excluded prior to analysis as their sedation failed. The total number of participants in each study were: K (7 participants), M (8 participants) and C (10 participants). Therefore, the sedation failure rate among the respective studied groups were K (30%), M (20%) and C (0%).

The demographic characteristics of the participants in the groups studied were comparable with no statistically significant difference between the groups. The ages of the participants ranged from 1week old to 2 1/2 years old with a mean age of 1.08 ± 0.79 years (table 4.3).

Three (3) out of every 5 recruited participants were females with majority (72%) of the participants having a head CT scan as their imaging procedure and 56% belonging to ASA II classification.

Adverse Events

Adverse events recorded in the current study are bradycardia, tachycardia, and excessive salivation. Forty percent (40%) experienced bradycardia and 28% tachycardia. Excessive salivation was least observed with an incidence of 8%. The incidence of these adverse effects between the groups studied was not significant (bradycardia, *p-value* =1.000, tachycardia, *p-value* =0.394 and excessive salivation, *p-value* =0.737).

Outcome

From the results of the study, intranasal ketamine, intranasal midazolam, and a combination of intranasal ketamine and midazolam produces:

1. A thirty percent (30%) intranasal ketamine failure rate, 20% intranasal midazolam failure rate and a 0% combination intranasal ketamine and midazolam failure rate.
2. Non-significant higher mean heart rates in the midazolam group as compared to the ketamine and the combination groups (*p*-value of 0.661).
3. Non-significant higher mean systolic blood pressures were recorded in the Ketamine group compared to the midazolam and ketamine-midazolam groups (*p*-value of 0.230).
4. Lower mean diastolic blood pressures were observed after the first 40 minutes of administration of intranasal midazolam compared to the ketamine and ketamine-midazolam groups. However, this was not significant (*p*-value of 0.721).
5. There was no significant difference in the observed mean oxygen saturations recorded among the groups (*p*-value = 0.694).

6. Non-significant (p-value = 0.211) higher mean respiratory rates were consistently observed over the 40min among the group C (combination of ketamine and midazolam) compared to the other groups
7. Administration of combination of ketamine and midazolam intranasally produced adequate sedation in the least time in comparison to intranasal midazolam alone and ketamine alone however this difference is not statistically significant (p-value = 0.168)
8. There was no statistically significant difference in the PSSS at the time of adequate sedation (p-value = 0.774)
9. Satisfactory separation of participants from their parents was observed in all three study groups
10. At the time of adequate sedation, a satisfactory acceptance of IV cannulation was obtained
11. No statistically significant difference in time to recovery was observed (p-value = 0.101). Participants in group K had the longest duration of recovery in comparison to group M with the shortest time to recovery.
12. The longest time to discharge was observed in the ketamine group whereas those who received intranasal midazolam had the shortest time to discharge. There was no statistically significant difference in the discharge times (p-value = 0.212).
13. Excessive salivation was noted among the groups that received intranasal ketamine alone and the combination of ketamine and midazolam. Other detected adverse events included tachycardia and bradycardia. All these adverse events observed were not statistically significant (p-value > 0.05) and did not require intervention.