CLINICAL STUDY REPORT

5/27/2015

Troypofol (Propofol 1 % Injection (10MG/ML)

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Clinical Study Report

INJECTION PROPOFOL 1% (10 MG/ML)

STUDY TITLE

An open label single arm single centre clinical study to evaluate the safety and efficacy of Troypofol (Propofol 1% (10mg/ml) injection) in induction of general anesthesia.

Principal Investigator	Designation
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INTRODUCTION

Propofol is a widely used intravenous anesthetic for induction as well as maintenance of general anesthesia. In everyday practice, a large inter individual variability in the induction dose of Propofol is noted with variation in induction dose, time to loss of consciousness, depth of sedation, incidence and magnitude of respiratory and hemodynamic side effects.[1] The literature reported wide variability in induction dose and induction time of propofol in various clinical trials.[1] Propofol given according to a preset regime may result in a higher incidence of adverse effects. Propofol should be administered to achieve specific induction or maintenance endpoints rather than being administered at a fixed dose.[2]

AIM

The objective of present study is to evaluate the safety and efficacy of Troypofol (Propofol 1% (10mg/ml) injection) in induction of general anaesthesia.

STUDY DESIGN

Open label, single arm, single centre clinical study

INCLUSION CRITERIA

- Patients scheduled for an intravenous induction of anesthesia with propofol
- Patients with American Society of Anesthesiologists (ASA) physical status I and II who are to undergo elective surgery
- Patients who are capable or willing to give the informed consent

EXCLUSION CRITERIA

- Patients with Allergy to propofol, or its excipients
- Patients with allergies to eggs, egg products, soybeans or soy products
- Pregnant or breastfeeding women
- History of central neurological disorder, epilepsy or brain injury
- Patients receiving psychotropic drugs
- Patient with a pacemaker
- Patients who are participated in any clinical trial within last 1 month
- Any disorder or condition that in the opinion of investigator would prohibit study participation or affect study outcomes

MATERIALS & METHODS

In this prospective observational study, Troypofol (Propofol 1% (10mg/ml) injection), India was given for induction by slow IV bolus or as decided as per standard hospital protocol. Medications considered necessary for the patients before and during the induction of anaesthesia as decided by the investigator are allowed and recorded in case record form. 'Dose of propofol (mg/kg) to obtain the induction of anaesthesia' and 'Time (seconds) to induction of anaesthesia after start of propofol administration' was recorded in CRF. Induction of anaesthesia was considered on occurrence of loss of verbal responsiveness (LOV), loss-of-eyelash reflex (LOE), and apnea. Adverse event noted by investigator during induction of anaesthesia was also recorded in CRF.

OBSERVATIONS AND RESULTS

Data of total 53 patients enrolled in the study was recorded in CRF. 11 patients were excluded from analysis due to incomplete CRF data. A total of 42 patients were undergone statistical analysis for safety and efficacy of propofol injection.

Demographic characteristics

A total of 42 patients completed the study. (Male – 15; Female – 27) Age of the patients enrolled in the study ranged from 3–99 years, the average age being 41.57 ± 26.28 yrs. (Table 1)

Table 1: Demographic characteristics

No. of Patients	42
Age (yrs) (Mean ± SD)	41.57 ± 26.28
< 55 yrs	29/42 (69.0%)
> 55 yrs	13/42 (31.0%)
Gender	
Male	15/42 (35.7%)
Female	27/42 (64.3%)
M:F Ratio	1: 1.8
Weight (kg) (Mean ± SD)	66.5 ± 15.6
Height (cm) (Mean ± SD)	161.0 ± 16.9

Required dose of Propofol

The propofol was used in induction of general anaesthesia for various types of surgical procedures in this study. Out of 42, 18 (42.9%) patients were evaluated for propofol efficacy & safety in orthopaedic/ musculoskeletal surgeries. Other surgeries were abdominal (11; 26.2%); oncological (8; 19.0%) and gynaecological (4; 9.5%). In one patient, propofol was used for induction during intubation procedure.

Overall dose of propofol required to produce induction of general anaesthesia in the study is 2.38 ± 0.51 mg/kg.

Table 2 represents the data obtained in this study in comparison with literature evidence.

Table 2: Study results – Comparison to literature evidence

Outcome	**This Study**	**Data reported in Literature**
Average induction dose of propofol	162.9 mg	141 mg[3] – 195.1 mg [4]
Variability in induction dose of propofol (SD)	46.7 mg	28.3 mg[4] – 60.9 mg[4]
Time to induction of anaesthesia after start of propofol administration	29.75 ± 1.09 seconds	2.2 ± 1.3 min[3]

As shown in Table 2, the dose of injection propofol 1% (10 mg/ml) required to produce induction in this study was comparable to those mentioned in literature and prescribing information of international brands.

Various studies reported wide inter-individual dose variability in induction dose of propofol, ranging from 1.4 mg/kg to 3.8 mg/kg. Induction dose of propofol reported in this study, i.e. 2.38 ± 0.51 mg/kg, fitted in the similar range. The induction dose of propofol injection in this study was similar to the induction dose 2.3 ± 0.8 mg/kg reported for other internationally available brand of propofol in literature.[3]

Time to onset of action

The average time to induction of anaesthesia after start of propofol administration reported in the study was 29.75 ± 1.09 s. The time of onset of propofol effect was same as reported in USFDA approved prescribing information of propofol brands i.e. 30-45 seconds. The time to loss of consciousness reported in literature varied from 0.6 to 5.0 minutes.[3] As shown in Table 2, this study showed faster onset of action with propofol compared to those mentioned in literature.

Adverse effects

No adverse effects were reported in the study. All the patients tolerated the procedure well without any complication during or after completion of procedure.

CONCLUSION

Troypofol (Propofol 1% (10mg/ml) injection) produced induction of general anaesthesia at the same dose and time as mentioned in the literature and prescribing information of other internationally available brands. It is found to be effective and safe for induction of general anaesthesia.

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no	PATIENT INITIALS	AGE (yrs)	Age Above 55 yrs	GENDER	HEIGHT(cms)	WEIGHT(kg)	AMOUNT OF PROPPFOL INJECTED (mg)	PROPOFOL INECTION DILUTED	DOSE OF PROPOFOL mg/kg	TIME OF ONSET OF EFFECT OF PROPOFOL (s)	Indication	TYPE OF SYRGERY		TIME OF START INJECTION	DURATION OF INJECTION
1	VLN	16	N	F	160	53	180	NO	3.40	25	Pelvic Pain	laparoscopy	Gynaec	7:10	15 S
2	J.J.L	35		M	NA	NA	2 vials	NO	NA	90 s	appendicitis	Appendicectomy		22:55	20 S
3	P.R.E	49	N	F	155	50	200	NO	2.00	30	AbnormalUterineBleeding	Diagnostic curettage and Legal	Gynaec	10:20	15 s
4		48		F	160	65	NA	NO	2mg/kg	30 S	Hiperplasia endometrial	Legrado		10:43	15 S
5	M.E.G	52		F			1	NO	180 mg	25 S	Umbilical Hernia	Umbilical Hemiorrafia		15:00	15 S
6	O.L	81	Y	F	148	58	100	NO	1.72	25	Intertrochanteric hip fracture, rightside.	open reduction	Ortho	10:30	10 S
7	C.M.D	55	Y	F	158	62	150	NO	2.42	30	Breaking of the left Radio.	open reduction internal fixation . General Anesthesia.	Ortho	8:55 AM	15 S
8	P.C.M	13	N	F	168	58	130	NO	2.24	30	Stab wound in the abdomen 30 cm.	Wash abdominal wall and raffia	abdominal	16:15	NA
9	MTO	84	Y	M	164	60	100	NO	1.67	30	Left humerus fracture	ORIF	Ortho	14:55	NA
10	BS	10	N	M	150	45	70	NO	1.56	30	Left radial fracture	open reduction and internal fixation	Ortho	7:45	It is intubated and continues with
11	G.M.A	40	N	F	158	65	140	NO	2.15	30	Nodule parathyroid	Under general anesthesia. Nodular region.	onco	7:45	NA
12	T.L	33		F	162	62	NA	NO	1.2 mg/kg	30 S	pregnancy 38,5 sem. Spontaneous pneumothorax	Caesarea		7:00 AM	NA
13	V. R	71	Y	F	160	90	200	NO	2.22	30	Left pyonephrosis	Left nephrectomy	abdominal	15:45	NA
14	N.O	51	N	F	168	68	150	NO	2.21	30	Parathyroid Adenoma right-thyroid nodule.	Resection of parathyroid adenoma thyroid lobectomy right straighter	onco	: 8:45	NA
15	M.I	77	Y	M	180	60	120	NO	2.00	30	Squamous Cell Carcinoma left temporal .	resection flap	onco	12:00	NA
16	C.M	54	N	F	155	61	100	NO	1.64	30	AbnormalUterineBleeding	Curettage and biopsy	Gynaec	10:10	6 Min. woke up
17	M.M	53		F		63	NA	NO	100 + 50 + 50	30 S	iirritable colon	Colonoscopy.		10:20 AM	
18	A.D	19	N	F	192	52	100	NO	1.92	30	incomplete abortion.	curettage	Gynaec	20:00	5 S
19	V.B	19	N	F	166	60	200	NO	3.33	30	Mammary Hypertrophy Gigantomasia	Breast Reduction	onco	8:00	Induction.

no	END POINT USED	CONCOMINANT MEDICINE USED	Opioids Y/N	OBSERVATION/REMARKS	Adverse events Y/N
1	Fentanyl and vecuronium bromide 150 3cc .	NA	Y	NA	N
2	NA	NA		NA	
3	Procedure is performed without complication patient tolerates procedure. Hypnosis good. He wakes up around 5:30	Fentanilo 100 mcg	Y	NA	N
4	written in french lang.	Fentanilo 100 mcg		NA	
5	16 + 10	NA		NA	
6	After spinal anesthesia by patient psychomotor excitation, it is decided intubate with 100 mg propofol.	NA	Y	NA	N
7	Intubation is performed with great hypnosis. Well tolerated .	Fentanilo 150 mcg Propofol 150 mg	Y	Anestesia general	N
8	Intubation for induction . General anesthesia.	Fentanile 100 mcg Esmeron 20.	Y	NA	N
9	Intubation without complication, general anhestesia Concomitant medicines used during	Fentanile 50 Norcuro 2	Y	NA	N
10	The intubation its been realized with out complications.	50 mg fentanyl Norcuro 2mg	Y	NA	N
11	Patient under general anesthesia induced with propofol. Uncomplicated intubation is performed similarly . Awakening quiet.	Fentanile 100mg Norcuron 2mg Remifentanil afterwards.	Y	NA	N
12	NA	33 patients undergoing cesarean section with		NA	
13	Obese, diabetic , hypertensive patient under general anesthesia induction with 200 mg of propofol. Intubation is performed with complete hypnosis . No complications.	100 mg of Fentanile, Nimbium 10mg and continue with	Y	Good response after two doses without complication	N
14	Patient undergoes from nasal intubation . No parameters are changed . No complications.	Fentanyl 100 Norcuron 3mg	Y	The product is generally carried out more remifentanil Isoflurane . Patient awake without complications.	N
15	Hypertensive patients , who treated diabetic induction for intubation is done keeping established parameters	Fentanilo- Nocurón 3mg. General anesthesia	Y	Quiet awake patient without complications	N
16	Patient tolerates uncomplicated procedure. Good induction.	Fentanilo 100mg	Y	NA	N
17	100mg induction colonoscopy is performed. It reinforces 50mg 6 minutes and 50 mg to 5 minutes. Patient wakes up within 15	Fentanile 100 mg		Patient awake well , no nausea, no vomiting.	
18	Uncomplicated procedure is performed.	Fentanilo 100 mcg	Y	NA	N
19	General Anesthesia. Induction intubation without complication. Good hypnosis.	Fentanilo 100 mcg Nocurón 4	Y	NA	N

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20	S.E	51	N	F	158	70	150	NO	2.14	30	Left urolitiasis	NA	abdominal	20:00	20:00 – 20:20
21	C.M	72	Y	M	168	70	200	NO	2.86	30	Cervical narrow channel	Cervical arthrodesis surgery	Ortho	10:10	2 hours surgery.
22	R.E	57			156	68	NA	NO	3mg/kg	30 s	Rupture of left rotator cuff.	Arthroscopy of the left shoulder.		7:20	induction of general anhestesia.
23	P.M	41	N	F	160	100	200	NO	2.00	NA	Right radial fracture	General Anesthesia. open reduction and internal fixation .	Ortho	9:00 AM	Patient could not be intubated after three trials.

no	END POINT USED	CONCOMINANT MEDICINE USED	Opioids Y/N	OBSERVATION/REMARKS	Adverse events Y/N
20	Hypertensive patients with arrhythmia 15 days ago. Sedation is performed to place double-J cathete	Morphine 3mg Buscapine.	Y	100 mg was placed and repeated 50mg 7 minutes . Normal respiratory patient hemodynamics, no complications.	N
21	General anesthesia. Induction intubation . He wakes up without complications.	Fentanile 100 Nocurón 5	Y	Patient is placed in prone position . Good awakening. Hemodynamically stable	N
22	General anesthesia induction by intubation.	Fentanile 100 Norcuron 4		Good induction. Hemodynamically stable patient . Wake up nice and quiet.	
23	NA	Fentanile 180 mcg Norcuron 3mg	Y	Obess patient , difficult intubation. Induction was performed and 3 intubation attempts are made for 6 minutes with out sucess. Laryngeal mask is placed . Tolerates uncomplicated event.	N

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24	S.C	84	Y	M	158	62	200	NO	1.5	30	Fracture of the left Radio.	osteolysis plus Reduction	Ortho	NA	INDUCTION, INTUBATION
25	M.E	60	Y	F	157	70	200	NO	2.86	30	fracture of the left radio	open reduction plus fixation	Ortho	10:50	Induction plus Intubation
26	B.M	21	N	M	168	70	200	NO	2.86	30	hypoxemia	hard intubation	Intubation	16:25	7
27	J.A	27	N	F	162	80	200	NO	2.50	30	fracture of the lef tibial discs.	Colocar tornillos	Ortho	8:30	induction and intubation.
28	A.E	46	N	M	175	90	200	NO	2.22	30	Acutecholecystitis	Gallbladder Removal	abdominal	16:10	2 sec
29	S.E	55		M	150	72	NA	NO	2 mg/kg	30 s	Radial Fracture	Open reduction and internal fixation		8:30	NA
30	V.J	18	N	M	168	70	200	NO	2.86	30	right olecranon fracture.	open reductionand internalfixation .	Ortho	10:50	intubation
31		13	N	F	100	41	100	NO	2.44	30	breast lump	Quadrantectomy	onco	18:15	Induction, laryngeal mask is placed.
32	A. S	15	N	F	167	70	150	NO	2.14	30	Apendicitis	Apendicectomy	abdominal	16:45	induction for gneral anesthesia
33		13	N	F	160	50	150	NO	3.00	30	mammary lumb.	quadrantectomy	onco	19:30	NA
34	B.Z	97	Y	F	148	50	100	NO	2.00	30	Incarcerated umbilical hernia	herniorrhaphy	abdominal	18:30	Induction single / 100 mg / laryngeal mask
35	G.M	17	N	M	169	80	100	NO	1.25	30	NA	Neck surgery . Emptying thyroid	onco	15:10	NA
36		26	N	M	172	70	200	NO	2.86	30	Right clavicle fracture	Under general anesthesia open reduction and internal fixation .	Ortho	7:25	NA
37	G.H	29	N	F	175	90	200	NO	2.22	30	Left clavicle fracture .	Open reduction and internal fixation .	Ortho	NA	NA
38	O.T	25	N	F	155	62	200	NO	3.23	30	Apendicytis	Apendicectomy	abdominal	19:45	induction and intubation.
39	A.A	78					100 mg	NO	1.5 mg	30 s	Chronic Subdural Hematoma	Trepano and drainage.		9:45	INTUBATION
40	I.A	57	Y	F	158	70	200	NO	2.86	30	cholecystitis	Colelaparoscopia	abdominal	15:00	Induction - Hypnosis - intubation
41					180	70	NA	NO	NA	30 s	Humeral Fracture by HDM	Reducción más osteosíntesis		7:30	NA

no	END POINT USED	CONCOMINANT MEDICINE USED	Opioids Y/N	OBSERVATION/REMARKS	Adverse events Y/N
24	Induction for general anesthesia. Good intubation is accomplished with hypnosis and uncomplicated	Fentanile 50 mcg Norcurón 3 mg	Y	NA	N
25	Induction -hipnosis - intubation without complications.	Fentanilo 100 mcg Norcuron 3 mg	Y	NA	N
26	ICU patient with 6-11 lethargy . Difficult intubation.	Propofol Lidocaine 150 mg plus 2.3 . 50 mg	N	Intubation accomplished, good hipnosis.	N
27	Induction , intubation for general anesthesia. No complications.	Induction with fentanyl and vecuronium	Y	wakes up good.	N
28	Under general anesthesia after induction was intubated without	fentanyl 150 lidocaine	Y	NA	N
29	Hypnosis by intubation was performed without complications.	Induction with fentanyl and propofol.		NA	
30	hipnosis by intubation is accomplished without complications.	fentanylvecuroniumbro	Y	NA	N
31	It makes hypnosis induction with only 100 mg, laryngeal mask is placed No. 3	Fentanile 100 Mantenimiento: Isorane y Remifentanile.	Y	NA	N
32	Hypnosis for intubation, general anesthesia without complications - induction is performed.	Fentanile 100 mcg Norcuron 3mg Manteinance with Isorane and	Y	wakes up good.	N
33	Intubation. Endotracheal tube is placed .	Fentanile 100, Norcuron	Y	NA	N
34	NA	Laryngeal mask was placed. Induction 100	N	NA	N
35	Induction intubation . General anesthesia without complication.	Fentanile 100 mcg, Esmeron 30 mcg.	Y	NA	N
36	Induction perfomed via hypnosis for intubation without complications. General Anesthesia	Fentanile 100 mcg Esmerón 30 mg	Y	General anesthesia. Awakening quiet uncomplicated .	N
37	General Anesthesia. Induction hypnosis for intubation is performed Without complications.	Fentanile 100 mcg Esmerón 30 mg Remifentanile Isorane	Y	Wake up very relax with out complications.	N
38	Hypnosis, intubation for general anesthesia.	Fentanyl 150 mcg over 4mg vecuronium bromide for induction .	Y	Intubation was performed without complications . Awakening nice.	N
39	Intubation and general anesthesia.	Fentanile 1,5 mg		NA	
40	Hypnosis, is intubated for general anesthesia without complications.	Induction with propofol, fentanyl and	Y	patients wake up relax and without complications.	N
41	Intubation was performed under hypnosis with propofol. Without complications.	Induction via Fentanile 150 mcg y Norcuron 4		Wake hemodynamically stable without complications.	

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42	M.Y	20	N	M	180	76	200	NO	2.63	30	Peritonitis by Appendicitis	Abdominal cavity wash	abdominal	18:25	Induction–Intubation.
43		27	N	M	165	76	200	NO	2.63	30	MPAF right humerus	Reduction place via Osteosynthesis	Ortho	17:10	Induction, hypnosis, intubation.
44	G.N	3	N	M	102	18	50	NO	2.78	30	Postoperative brain tumor	Place slope catheter.	onco	11:30	Intubation
45				F	158	50	150 mg	NO	3 mg/kg	30 S	fracture of the left femur	Reduction.		9:35	NA
46	B.C	45	N	F	162	80	200	NO	2.50	30	Right humerus fracture	open reduction with internal fixation .	Ortho	12:30	NA
47	G.C	30	N	M	182	90	200	NO	2.22	30	Wounded by slashing weapon in right hand	Review, washing and tenorrhaphy	Ortho	15:05	NA
48	R.M	87		F	148	45	NA	NO	2mg/kg	30 S	Subdural hematoma	Trephine plus drainage		15:30	Intubation
49	G.R	21	N	F	168	75	200	NO	2.67	30	wound in right knee.	Washing and debridement of the right knee.	Ortho	NA	NA
50	G.R	64	Y	F	162	70	200	NO	2.86	30	fracture of left kit.	open reduction plus internal fixation .	Ortho	14:15	intubation
51	H.Y	20	N	F	180	70	200	NO	2.86	30	peritonitis	Washing and review.	abdominal	14:00	induction and intubation
52	G.C	66	Y	M	160	85	200	NO	2.35	30	Right ulnar radius fracture.	open reduction and internal fixation.	Ortho	12:20	induction plus intubation.
53	O. M	99	Y	F	140	48	100	NO	2.08	30	Apendicitys	Apendicectomy	abdominal	17:50	induction and intubation.

no	END POINT USED	CONCOMINANT MEDICINE USED	Opioids Y/N	OBSERVATION/REMARKS	Adverse events Y/N
42	Hypnosis - intubation for general anesthesia.	Fentanile, Rocuronion.	Y	NA	N
43	Iintubaions with out complications.	Fentanile 100 mcg Norcuron 4mg Manteincance with Isorane and Remifentanile.	Y	NA	N
44	Intubates with TOT 3.5 Induction with 50 mg of propofol.	NA	Y	procedure without complications	N
45	Induction, intubation, general anhestesia.	Fentanile 100 mcg Norcuron 4 mg		Wake up early with out complications.	
46	Induction- intubation for general anesthesia.	Fentanyl100 mcg Norcuron 4 mg	Y	NA	N
47	Induction, intubation was performed under general anesthesia.	Fentanile y Norcuron	Y	wake up well.	N
48	Induction , intubation without complications	Fentanile.		NA	
49	Induction, laryngeal mask placed # 4 for general anesthesia.	Fentanile 100	Y	NA	N
50	Induction and intubation for general anesthesia. Patient psychiatric disorder	Fentanyl 100 and ESMERON 30	Y	wakes up good with out complications.	N
51	Induction for intubation with general anesthesia.	Fentanyl 150 mcg Norcuron 3 mg	Y	wakes up relax and without complications.	N
52	Induction - intubation for general anesthesia without complications was performed.	Fentanyl 150 mcg y Norcurón 4 mg	Y	Induction - intubation was performed without complications . Awakening hemodynamically stable.	N
53	Induction - intubation for general anesthesia	Fentanyl 50 mcg Norcurón 2 mg	Y	He wakes quiet, hemodynamically stable.	N