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Review Article

Camylofin dihydrochloride injection: a drug monograph review

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ABSTRACT

Camylofin dihydrochloride is an anti-spasmodic drug available in India and other Latin American and African countries, for the treatment of abdominal colic and for acceleration of labor. Although, the drug has been in use for over six decades, with multiple citations in academic text books of repute, treatment protocols, and multiple research publications, there is no consolidated published information on the pharmacology and clinical details of camylofin. This drug statement/monograph is an attempt to collate and present scientific information that will come in handy to practicing obstetricians and gynaecologists, as well as other primary care physicians, when treating cases of abdominal colic or managing prolonged labor. Approved clinical indications, clinical pharmacology, dosage, contraindications, precautions, drug interactions, adverse effects, overdose and clinical evidence in different indications are covered herein.

Keywords: Anti-spasmodic, Augmentation of labor, Camylofin, Cervical dilatation, Drotaverine, Hyoscine, Spasmolytic, Valethemate

INTRODUCTION

Camylofin dihydrochloride is an anti-spasmodic drug available in India and other Latin American and African countries, for the treatment of abdominal colic and for acceleration of labor.[1,2] Although, the drug has been in use for over 60 years, with multiple citations in academic text books of repute, treatment protocols, and multiple research publications, there is no consolidated published information on the pharmacology and clinical details of camylofin.[3-13]

This drug statement/monograph is an attempt to collate and present scientific information that will come in handy to practicing obstetricians and gynaecologists, as well as other primary care physicians, when treating cases of abdominal colic or managing prolonged labor.

Chemical description

Camylofin dihydrochloride is an effective synthetic spasmolytic that was first introduced by Brock in 1950.[3,4]

It was initially available in India under the name 'Avacan' (Innovator and Registered trade mark of Asta-Werke A.G, Germany) since 1958 and currently available under the trade name of Anafortan (Abbott Healthcare Pvt Limited).[3,4,14,15]

Camylofin dihydrochloride is 3-methyl butyl 2-(2-diethyl amino ethyl amino)-2-phenyl acetate hydrochloride. It belongs to the group of spasmolytic, anticholinergic and gastro intestinal sedative drugs. It has a molecular formula of $C_{19}H_{32}N_2O_2 \cdot 2HCl$ and a molecular weight of 393.4. Its structure is depicted in Figure 1.[16]

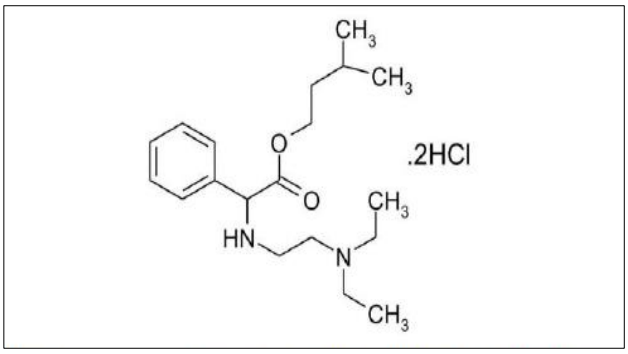

Figure 1: Structure of Camylofin dihydrochloride (C19H32N2O2.2HCl).

COMPOSITION[17]

Camylofin is available as a 2ml ampoule and a 20ml vial for injection

Each ml of the product contains:

- Camylofin dihydrochloride: 25 mg
- Benzyl Alcohol (as preservative) IP: 2% w/v
- Water for injection IP: q.s

INDICATIONS AND CLINICAL USE

Camylofin Injection is indicated for the symptomatic relief in the treatment of abdominal colic or abdominal spasmodic pain originating from various abdominal viscera. Conditions where camylofin injection is likely to provide symptomatic relief include gastro-intestinal colic, ureteric or renal colic, biliary colic and menstrual colic or pain associated with primary dysmenorrhea. Camylofin injection can be given to adults for treating abdominal colic. There is no specific contraindication for its use in children, however, there is no data establishing the safety and efficacy of camylofin injection in children less than 12 years.[17,18]

Camylofin Injection is also indicated in 1st stage of active phase of labor for acceleration of labor. Camylofin injection is given during active phase of labor to accelerate labor (when necessary) generally at 3cm of cervical dilatation.[17,18]

Camylofin injection is also used as per the protocols of active management of labor for the aforesaid purpose. Here it is given along with an analgesic agent like tramadol, as the combined drug effect is considered to provide good analgesia, in addition to improving the cervical dilatation.[11,12] Camylofin injection can be used for augmentation of labor in both primigravida and multigravida women. Camylofin shortens the duration of labor in primigravidas by almost 40% and multigravidas by almost 24%. It can also be used in cases of uterine inertia.[13] There is no strong clinical trial evidence to recommend the use of camylofin in other indications associated with abdominal pain like spastic constipation, gastritis, peptic ulcer etc.

PHARMACOLOGY

Mechanism of action

Camylofin is a spasmolytic agent with a potent dual mode of action, i.e. it possesses both musculotropic and neurotropic effects. This dual mode of action has been demonstrated in animal experiments, where in camylofin abolished the spasm inducing effects of both carbachol (cholinergic spasms) and barium chloride (muscular spasms.[13,19-21]

Musculotropic action

Camylofin has a direct papaverine like spasmolytic action on smooth muscles, where it inhibits the enzyme phosphodiesterase IV, which in turn causes an increase in intracellular concentration of cyclic AMP and smooth muscle relaxation by depletion of intracellular calcium levels. This is the more predominant action of camylofin.[13,19-21]

Neurotropic action

Camylofin also possesses a neurotropic action i.e. a mild atropine like anti-cholinergic effect, where by it causes smooth muscle relaxation, by inhibiting the binding of acetylcholine with the muscarinic receptors. Unlike the musculotropic action which is comparable to papaverine, the neurotropic action is only 1/7th that of the potency of atropine.[5,13,19-21]

Hence, camylofin overall, has a comprehensive and potent spasmolytic action on the smooth muscles of the viscera (Gastrointestinal, renal, biliary tracts) and cervix, but its action on the glands, eyes, heart and circulation is minimal.[13,19-21]

Mode of action of camylofin in spasmodic pain or colic of abdominal viscera

By definition, colicky pain results to due to excessive contraction and spasm of smooth muscles of a hollow viscera (intestine, ureter etc). Therefore, camylofin due to its potent dual anti-spasmodic action, acts on these smooth muscles and relaxes them and thereby provides relief from the associated colicky pain.[8,22,23]

Mode of action of camylofin in cervical dilation for augmentation of labor

Cervical dilatation is one of the important factors, which determines the duration of labor. Labor is associated with a fear-tension-pain syndrome, which results in increased tone of the muscles of the cervix. Excessive stimulation of the motor mechanism of the sympathetic nervous system increases the tone of the circular muscle fibres of

the cervix. Resistance in these muscles produces pain by stimulating the sensory nerve endings. Thus, there is a painful spasm of the cervix, prolonging the labor.[13,20]

Here again, camylofin primarily acts on the smooth muscles of the cervix. This action of camylofin is unique since, it is a preferential cervical dilator, i.e. it has no interference on the uterine contractions. Although camylofin possesses a musculotropic action, it does not interfere with uterine contractility due to its phosphodiesterase IV iso-enzyme selectivity. Owing to this unique preferential cervical dilating action, camylofin can be recommended for use in accelerating the first stage of labor. [13,20]

Onset of action

After a single intramuscular injection of 50mg of camylofin dihydrochloride, the onset of action begins in 15 to 20 minutes. The route of administration may also determine the quickness of onset of action. Intramuscular administration provides relatively slower onset of action compared to intravenous administration. However, there is very limited experience with the use of camylofin in the intravenous route and is hence recommended to be given through intramuscular route only.[5,18]

Duration of action

After a single intramuscular injection of 50mg of camylofin dihydrochloride, the action lasts for 4-5 hours. In clinical studies evaluating acceleration of labor, camylofin showed superior results with just a single dose compared to other molecules like drotaverine, hyoscine and valethemate, where multiple (2-3) doses are required, sometimes at hourly intervals.[5,13]

Metabolism and elimination

Parenterally administered camylofin is rapidly distributed in the body to various tissues. Most of the tissues (highest in liver), with the exception of the gastrointestinal tract (least), possess an esterase enzyme which cleaves camylofin into two pharmacologically weak metabolites (isoamylalcohol and alpha -N-(beta -diethyl aminoethyl)D-amino- phenylacetic acid. Camylofin is rapidly metabolized and only a small amount of it is excreted into the urine.[4]

DOSAGE AND ROUTE OF ADMINISTRATION

Abdominal colic

In abdominal colic, depending upon the severity of pain, 1 -2 ampoules (i.e. 50mg to 100mg) to be given as an intramuscular injection only. As mentioned in earlier sections, there is limited data to suggest the safety and efficacy of camylofin injection in the intravenous route. In one clinical study enrolling adult patients with colicky abdominal pain, camylofin injection was administered as a slow intravenous injection given over one-minute duration. The study did not report any serious adverse effects. However, camylofin injection is recommended to be administered as an intramuscular injection only.[17,18]

Active phase of labor

In active phase of labor, camylofin injection is given as an intramuscular injection, usually at 3cm cervical dilatation. One injection is sufficient for effective results in active phase of labor, however a repeat dose may be given if required. Different clinical studies have selectively employed the use of a repeat dose after one hour, two hours and three hours of the initial dose. The number of doses in these studies ranged from one dose to a maximum of four doses. These studies have not reported or highlighted any specific adverse events related to the higher dose used in these subjects.[5,17,24-27]

CONTRAINDICATIONS

Camylofin injection is contraindicated for use in the following conditions[17]:

- Hypersensitivity to camylofin or any of ingredients
- Narrow-angle glaucoma
- Prostatic hypertrophy
- Mechanical stenoses.
- Mega colon
- GI hemorrhage
- Tachyarrythmia
- Porphyria
- Urinary retention.

WARNINGS AND PRECAUTIONS

Camylofin injection must be used with caution in patients with thyrotoxicosis, obstructive lung disease, during cardiac surgery or those with fever. It should be used with caution in elderly, in patients with urinary retention, prostatic enlargement, tachycardia, cardiac insufficiency, paralytic ileus, ulcerative colitis and pyloric stenosis, pregnancy and in breast feeding.

Camylofin injection should be co-administered with caution in patients taking amantadine, quinidine and tricyclic antidepressants.[16,17]

PREGNANCY AND LACTATION

There is no data on the safety and efficacy of camylofin injection in pregnant women. Hence, it is not recommended for use in pregnancy. However, camylofin injection can be used for augmentation of labor. There is efficacy and safety data for both mother and children in this clinical setting.There is no data on the safety and efficacy of camylofin injection in lactating women. Hence, it is not recommended for use in lactating mother.[16,17]

DRUG INTERACTIONS

The important drug interactions are listed below

- Antacids interfere with absorption of camylofin.
- Antihistaminics, tricyclic antidepressants, phenothiazines, disopyramide, pethidine have anticholinergic property-additive effects which occur with camylofin.[16,17]

ADVERSE REACTIONS

Camylofin injection may cause skin rashes, other allergic reactions and infrequently atropine-like side effects.

In clinical studies where camylofin injection was evaluated for augmentation of labor, the following adverse effects were reported, (none of them being reported as serious in nature).

Maternal adverse effects

Nausea, vomiting, dryness of mouth, tachycardia, palpitations, giddiness, drowsiness, dilatation of pupils.

In addition, few cases of atonic post-partum haemorrhage, cervical tear, vaginal tear, retained placenta, secondary arrest of cervical dilatation were also reported.

Foetal adverse effects

Foetal distress, meconium stained liquor. While a low APGAR was recorded in few cases, the APGAR score was found to be normal in most of the subject babies.[13,17,18,20,24-28]

OVERDOSE AND TREATMENT

Camylofin has a wide margin of safety. The ratio of the effective therapeutic dose to the toxicity dose in animal studies varies from 1:40 to 1:150.5.[13,20]

Symptoms of overdose

The following symptoms have been observed with an overdose of camylofin-dry mouth, difficulty in swallowing and talking, flushed and hot skin (especially over face and neck), fever, difficulty in micturition, decreased bowel sounds, dilated pupil, photophobia, blurring of near vision, palpitation and a scarlet rash may appear.

In a few cases reported in neonates and children (oral use), severe intoxication may resemble opioid intoxication.[17,29]

Treatment of overdose

In case of an overdose, discontinue the medication, treat symptomatically, and institute supportive measures as required. There is no evidence in adults, but there is evidence, although limited, to suggest management of a case of overdose of camylofin in neonates with naloxone i.v (0.02mg/kg body weight), leading to a prompt improvement in clinical picture. Naloxone is an opioid antagonist. In some cases, multiple doses of naloxone may be needed.[17,29]

FORMULATIONS AND STRENGTHS[17]

Camylofin dihydrochloride injection is available as

- A single use ampoule containing 2mL of camylofin dihydrochloride.
- A multi-dose vial containing 20mL of camylofin dihydrochloride.

An injectable formulation of camylofin dihydrochloride (50mg) and diclofenac sodium (50mg) is also available.

CLINICAL STUDIES

The role of Camylofin as an antispasmodic in pain relief as well as in acceleration of labor was demonstrated as early as 1950. Table 1 and 2 lists the various publications in this regard.

Table 1: Publications on Camylofin.

Investigator	Publication title
Brock N	Pharmacology of Avacan[3]
Pezold FA	Spasmolysis (Clinical experience with a new spamolytic Avacan)[30]
Helmut K, Krentz C	Clinical results with a new spasmolytic (Avacan)[31]
Stoll HG	Clinical experiences with Avacan in urological diseases[32]
Hiller J, Strauss E	Effect of Avacan on peristalsis of upper intestinal tract and on gastric secretion[33]
Sielaff HJ	Comparative experimental studies on the effect of spasmolytics and ganglion-blocking substances (atropin, avacan, pendiomid, buscopan, banthine) on motility of the human small intestine[34]
Pilz A	Clinical experience with a new spasmolytic (Avacan)[35]
Hasselbacher K	Cystometric studies after administration of Avacan[36]
Gupta C	Use of Anafortan intravenous injection for treatment of colicky pain[18]

Table 2: Publications on Camylofin for obstetric use.

Investigator	Publication title
Boldt W, Gocht W	The use of Avacan in speeding of delivery[37]
Guseck E	Conservative speeding of delivery by Avacan[38]
Asholter C	Acceleration of delivery by Avacan[39]
Drescher H	Experience with the spasmolyticum Avacan in obstetrics[40]
Jann R	Experience with the spasmolytic Avacan in obstetrics[41]
Etterich M, Mall-Haefeli M	The effect of spasmolytic agent on parturition[42]
Rehsteiner HP	Comparative study on the labor-analgesic effect of Vendal and Centralgin-Avacan[43]
Auclair JM, Anton JP et al.	Study of the action of the association of glyceric ether of guaiacol and camylofine on the dilatation of the cervix during the labor[44]
Warke HS, Chauhan AR	A randomised double-blind trial* (*Camylofin Vs Placebo)[20]
Kaur D, Kaur A	"Anafortan" an old drug with its newer use in acceleration of labour[28]
Kaur S, Bajwa S et al	To compare the effect of Camylofin dihydrochloride (Anafortin) with combination of Valethamate bromide (Epidosin) and Hyoscine Butyl-N-Bormide (Buscopan) on cervical dilation[25]
Rajani Uday, Binu P	A randomized comparative study of intramuscular Camylofin dihydrochloride and intravenous Drotaverine hydrochloride on cervical dilatation in labor[26]
Dayama S, Patil S et al	A randomised controlled study of intramuscular Camylofin dihydrochloride vs intravenous Hyoscine butylbromide in augmentation of labour[24]
Mayadeo N, Gangadhar A et al	Camylofin in the management of prolonged labor: a review of evidence[13]

Clinical evidence in abdominal colic

The clinical efficacy and tolerability of camylofin injection was studied by C. Gupta, 2000 in 209 Indian patients in a multi-centric trial involving 35 investigators. The study enrolled 73 patients of intestinal colic, 88 patients of renal colic, 36 patients of biliary colic and 12 patients of menstrual colic. Table 3 summarizes the results of this study. Overall, the study reported a good response to camylofin therapy in 95% of the patients. Overall, 67 (91%) of these patients reported good pain relief after treatment with camylofin. Overall, 83 (94%) of these patients reported good pain relief after treatment with camylofin. In 29 patients, the dose of camylofin had to be repeated. Overall, 33 (91%) of these patients reported good pain relief after treatment with camylofin. In 15 patients, the dose of camylofin had to be repeated. Lastly, in patients with menstrual pain, 12 (100%) of these patients reported good pain relief after treatment with camylofin, with a repeat dose given in 2 patients.

Thus, the investigators concluded that camylofin injection is a very effective treatment for symptomatic relief of abdominal colic, with relatively few and mild adverse effects.[18]

Table 3: Summary of the results of the study by Gupta C.[18]

Anafortan injection in colic of various origins		
Study details	**Study interventions**	**Study results: good pain relief in**
The clinical efficacy and tolerability of Camylofin injection was studied by Gupta C, 2000 in 209 Indian patients in a multi-centric trial involving 35 investigators.	The study Intervention involved camylofin 25mg (1ml). However, this is only half of the generally recommended dosage of camylofin injection which is 50mg (2ml).	Intestinal colic: 91% Renal colic: 94% Biliary colic: 91% Menstrual colic: 100%

Clinical evidence in augmentation of labor

There is ample evidence to support the efficacy and tolerability of camylofin injection in the active management of labor.

Published evidence suggests that camylofin has superior efficacy in augmentation of labor on multiple counts like rate of cervical dilation, duration of active phase of first stage of labor and induction delivery interval, when compared to other spasmolytics like drotaverine, hyoscine and valethemate. It also has a benefit of a convenient single dose.

Camylofin has other advantages like a quick onset of action, prolonged action, no adverse effects on uterine contractility, no contraindication for use in uterine inertia cases and overall good tolerability for both mother and foetus.

Table 4 summarizes the clinical trial evidence on camylofin in augmentation of labor.[13]

Table 4: Summary of clinical trial evidence on camylofin in augmentation of labor.[13,20,24,26-28]

Investigator	Study design	Comparator drugs/ dosage used	Results				Conclusion
			Cervical dilatation rate	**Duration of active phase of labor**	**Total duration of labor**	**Other findings**	
Dayama S	Randomized, controlled study (n=150)	Camylofin (I.M-Repeated hourly- Max 4 doses) vs Hyoscine (I.V-Repeated hourly- Max 4 doses)	3.14 cm/hr vs 2.78 cm/hr (P<0.001)	118m vs 130m (p<0.01)	Not Reported	Significant shortening of the 3rd stage of labor also in Camylofin group	Camylofin is superior to Hyoscine
Uday R	Randomized, controlled study (n=126)	Camylofin (I.M-Repeated after 2 hours) vs Drotaverine (I.V-Repeated after 2 hours)	1.78 cm/hr vs 1.61 cm/hr (P=0.002)	333m vs 357m (p=0.142)	379m vs 395m (p=0.207)	Patients needing second dose: 5% vs 92% (P<0.001)	Camylofin is superior to Drotaverine
Kaur S	Randomized, controlled study (n=200)	Camylofin (I.M-Single dose) vs Hyoscine + Valethemate (I.M-Repeated after 1/2 hours-Total 3 doses)	3.33 cm/hr vs 2.69 cm/hr (P<0.01)	141m vs 181m (p<0.01)	Not reported	Induction-Delivery Interval 172m vs 211m (p<0.01)	Camylofin is superior to Hyoscine + Valethemate
Kaur D	Randomized, controlled study (n=100)	Camylofin (Single dose) Vs Hyoscine (Repeated after 1hour-Total 3 doses)	Not reported	Not reported		Induction-Delivery Interval is significantly shortened in camylofin group	Camylofin is superior to Valethemate
Warke H	Randomized and Double-blind study (n=100)	Camylofin (I.M single dose) vs Placebo	1.92cm/hr vs 1.18 cm/hr (p<0.001)	3h35m vs 5h34m (p<0.001)	4h42m Vs 6h31m (p<0.001)	No effect on the uterine activity	Camylofin is superior to Placebo

PROGRAMMED LABOR/ ACTIVE MANAGEMENT OF LABOR-ROLE OF CAMYLOFIN

Need for programmed labor/ active management of labor

Labor and delivery-related complications being the largest contributors to India's high maternal mortality rate, optimizing labor and delivery are of utmost importance.

The stress of labor causes release of catecholamines, which may lead to a dysfunctional labor and compromised foetal oxygenation. This rise in catecholamine secretion can be reduced by the synergistic use of analgesics and antispasmodics in the active phase of labor. Warke et al reported that camylofin dihydrochloride accelerates labor by regulating the autonomic system and thus the disordered progress of labour is normalised. This facilitates the cervical effacement and dilatation.[11,12,20]

Active management of labor

Active management of labor was a concept advanced by the Irish school. Driscoll et al reported on the advantages of active management of labor resulting in shorter labor, improved obstetric outcome and lowered cesarean section rates.[11,12,20]

Programmed labor

Programmed labor is an indigenously developed protocol for labor management (Daftary et al 1977), developed with the dual objective of providing pain relief during labor and reaching the goals of safe motherhood by optimizing obstetric outcome.[11,12]

Programmed labor concept

The protocol developed by Daftary et al, over a period of many years rests on three pillars of[11,12]:

1. Ensuring adequate uterine contractions-Active management of labor.
2. Providing optimum pain relief-Use of analgesics and antispasmodics.
3. Close clinical monitoring of labor events-Maintaining a Partogram.

Clinical evidence on Camylofin in active management of labor/ programmed labor

Bachani et al, conducted a study to analyse the safety and efficacy of active management of labor at a secondary hospital using the protocol proposed by Daftary et al.[12]

Women in labor with a term pregnancy were enrolled in the study in two groups. The study group managed with the active management of labor protocol and the control group which was managed expectantly.

The two groups had 700 subjects each and were similar regarding parity, age, and pregnancy-related complications such as pregnancy-induced hypertension, and intrauterine growth retardation. The study intervention involved:

- A gel preparation containing 0.5 mg of prostaglandin E2 was instilled intracervically in women with a Bishop score of 6 or less.
- Oxytocin was administered for labor augmentation, if necessary.
- The partogram was then started, and amniotomy performed.
- At the onset of the active phase of labor, 6 mg of pentazocin (an opioid analgesic) and 2 mg of diazepam (a tranquilizer) were diluted in distilled water and administered intravenously, and 50 mg of camylofin dihydrochloride (a smooth muscle relaxant) was administered intramuscularly.
- Three hours later an injection of tramadol hydrochloride (an analgesic) or drotaverine hydrochloride (an antispasmodic) was given, the latter being repeated every 2 h depending on the partogram and the patient's pain score.
- An injection of 125 mg of carboprost tromethamine was given intramuscularly after delivery to promote contraction and retraction of the uterine musculature.
- The remainder of the pentazocine and diazepam mixture was injected while the episiotomy was being sutured.

The study results suggested that in the study group (compared to the control group)

- The duration of all stages of labor was reduced in both primiparas and multigravidas.
- Definite reduction in pain and blood loss and no adverse effects.
- The mean rate of emergency cesarean deliveries was 17.85% Vs 28.38% ($p<0.05$)
- There were no maternal deaths and perinatal mortality was 2.6 per 1000 live births in the study group.

Table 5: Results of the study by Bachani et al.12

Mean labor duration	Study group (n=700)		Control group (N=700)	
	Primiparas	**Multiparas**	**Primiparas**	**Multiparas**
1st stage, h	6.2	3.5	7.5	4.2
2nd stage, h	2.1	1	2.5	1.5
3rd stage, min	3.5	3	10	8

Duration of labor among women who had active management of labor (study group) and women who had expectant management (control group)

The investigators concluded that active management is a safe and effective labor protocol to follow in a secondary setting where advanced facilities, such as an intensive care unit and a blood bank, are not available. Daftary et al reported the results of an open, prospective (Between January 2000 to December 2007), randomized, parallel group, monocentric, comparative matching trial assessing the labor outcomes using a programmed labor protocol. 200 subjects were enrolled in each group, aged between 21-30 years, as low risk parturient. Study interventions included partography, oxytocin, primiprost, pentazocin, diazepam, tramadol, drotaverine/ camylofin / hyoscine / valethemate and ketamine.[11]

Study results showed that the programmed labor group had:

a. Shorter mean duration of active labor 3.5 hrs (vs 5.2 hrs in the control group.)
b. Higher cervical dilatation rate of 2.5 cm/hr (vs 1.2 cm/hr in the control group.)
c. Shorter mean duration of 2nd stage of labor 26mins (vs 48mins in the control group.)
d. Shorter mean duration of 3nd stage of labor 3.5mins (vs 15mins in the control group.)
e. Average blood loss of 60mL (vs 120ml in the control group.)
f. Pain relief:
   i. Excellent 24% (vs 0% in the control group)
   ii. Substantial 62% (vs 32% in the control group)
   iii. Insufficient 14% (vs 56% in the control group)
   iv. No pain relief 0% (vs 12% in the control group).

The investigators thus concluded that with programmed labor using the indigenous protocol can result in progressive, shorter, and comfortable labor, with lesser blood loss.

STORAGE CONDITIONS

Camylofin Injection should be stored at a temperature not exceeding 30°C and protected from moisture.[17]

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Conflict of interest: None declared
Ethical approval: Not required

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