

# CLINICAL TRIAL OF "CALCI V"

# Evaluation of the efficacy of "CALCI V", in the management of "Calcium Supplement and other benefits"

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## Reason: (HETU)

Ayurved is a science that considers any disease from its origin to its treatment. It is to prevent disease from its recurrence. This is the need of today's mankind suffering from various diseases to get treated by natural way of healing. So is our step further to use modern technology, knowledge available, diagnostic help combine with Non Toxic, Non Narcotics, Non Metallic, Non Animal ingredient, purely Herbal Ayurvedic formulations to achieve this goal.

## Introduction: (Prastavana)

Calcium is a mineral found in many foods. The body needs calcium to maintain strong bones and to carry out many important functions. Not having enough calcium can cause many health problems. Calcium insufficiency also causes weak bones and tooth decay. This is because almost all calcium is stored in bones and teeth. This clinical trial is to understand the importance of calcium in the body and how one can get right amount of it.

#### Usage of Calcium (Upruktata):

One has more calcium in his or her body than any other mineral. Calcium has many important jobs. The body stores more than 99% of its calcium in the bones and teeth to help make and keep them strong. The remaining 1% of the calcium in the body is found in blood, muscles, and the fluid between cells. His or her body needs this 1% of calcium to help muscles and blood vessels contract and expand, to secrete hormones and enzymes, and to send messages through the nervous system. It is important to get plenty of calcium in the foods you eat.

#### Average need of Calcium (Praman):

The amount of calcium a person needs depends on his or her age and other factors. Growing children and teenagers need more calcium than young adults. Older women need plenty of calcium to prevent osteoporosis. People who do not eat enough high-calcium foods should take a calcium supplement. The body continuously removes and replaces small amounts of calcium from the bones. If more calcium is removed than is replaced, bones become weaker and have a greater chance of breaking. This is known as osteopenia and osteoporosis. If you get enough calcium from the foods you eat and drink, his or her body doesn't have to take the calcium away from his or her bones and bones can stay strong. In fact, getting enough calcium at a young age can help prevent osteoporosis.

# Importance of Calcium: (Karmukta)

Calcium can help build strong teeth. Both baby teeth and adult teeth need calcium to grow and develop. Calcium can help protect teeth against tooth decay. It also helps make gums healthy and makes jawbones strong. The remaining 1% of the calcium in the body is found in blood, muscles, and the fluid between cells. The body needs calcium to help muscles and blood vessels contract and expand. Calcium also helps the body secrete hormones and enzymes and send messages through the nervous system.

# Symptoms of calcium deficiency : (Asthi Kshay Lakshan)

- Not getting enough calcium is called calcium deficiency. Without enough calcium, bones and teeth will become weak and more likely to break or decay. Calcium deficiency can cause osteoporosis or osteopenia.
- Osteoporosis is a condition in which bone density decreases, causing bones to become fragile. Low bone mass that is not low enough to be osteoporosis is sometimes called osteopenia.
- Calcium plays an important role in the functioning of muscles and nerves, its deficiency causes problems in the muscular and nervous systems. Symptoms of such problems include numbness and tingling in the fingers, convulsions, and abnormal heart rhythms. Serious calcium deficiency can lead to death if not treated.
- A lack of vitamin D can cause rickets, a disease where the bones become soft and weak causing the bones in the legs of infants to bend.

# Average Calcium requirement per day (Prati Din Avashyakta)

- The amount of calcium a person should take each day is described in milligrams, or mg. The recommended amount per day depends on the age, gender, and health of the person.
- ✓ From birth to 6 months the recommended amount per day is 200 mg.
- $\checkmark$  For infants 7 to 12 months, the recommended amount is 260 mg.
- ✓ Children 1 to 3 years of age should get 700 mg of calcium daily.
- ✓ From 4 to 8 years of age the daily recommended amount is 1,000 mg.
- ✓ Children and teens 9 to 18 years of age need 1,300 mg.
- ✓ For adults 19 to 50 years of age, the recommended daily amount is 1,000 mg.
- $\checkmark$  The daily recommended amount for adult men 51 to 70 years of age is 1,000 mg.
- ✓ The daily recommended amount for adult
- ✓ women 51 to 70 years of age is 1,200 mg.
- ✓ Adults 71 years of age or older, the daily amount is 1,200 mg.

 ✓ Pregnancy does not affect the amount of calcium needed each day. Pregnant women should get the recommended amount for their age group.

The following groups of people are at higher risk of not getting enough calcium from the foods they eat:

- Boys 9 to 13 years old
- Girls 9 to 18 years old
- Women older than 50 years
- Men older than 70 years

## Causes of Calcium deficiency :( Karan):

- Older adults, especially women after menopause
- Older adults who have broken a bone
- Women who experience early menopause
- Thin people who have small bones
- People with a limited diet
- Diet excluding dairy products
- Certain medical conditions. Examples include: Rheumatoid arthritis, Thyroid disorders, Seizure disorders, Gastrointestinal diseases, lack of vitamin D.

## Prevention of Calcium (Sthapana):

The body continuously removes and replaces small amounts of calcium from the bones. If more calcium is removed than is replaced, bones become weaker and have a greater chance of breaking. This is known as osteopenia and osteoporosis. If one gets enough calcium from the foods he or she eat and drink, his or her body doesn't have to take the calcium away from his or her bones and bones can stay strong. In fact, getting enough calcium at a young age can help prevent osteoporosis.

#### Sources of Calcium (Uplabdhta):

- One can get calcium in two ways: through the foods and from supplements. Calcium is found in many foods. One can get recommended amounts of calcium by eating a variety of foods, Milk, yogurt, and cheese are the main food sources of calcium for the majority of people.
- Milk also has added vitamin D, which is important for helping his or her body better absorb calcium.
- Calcium can also be found in leafy, green vegetables. Drumsticks, broccoli, and Chinese cabbage are good vegetable sources of calcium.
- > Nachani, Ragi, Soya and other grains
- Fortified foods with calcium include some breakfast cereals, fruit juices, soy and rice beverages, and tofu.
- Calcium is included in most multi-vitamins. Supplements that contain only calcium or calcium with other nutrients

> The body can also make some vitamin D when it is exposed to the sun.

# Calcium Toxicity (Asthi Dhatu Vishaktata)

While it is uncommon to take in too much calcium, it is still possible. Calcium toxicity is usually caused by taking too many supplements. Calcium toxicity is not usually caused by getting too much calcium from food sources. Too much calcium can cause constipation. It might also interfere with the body's ability to absorb iron and zinc. Inadults, too much calcium from dietary supplements might increase the risk of kidney stones. Too much calcium from food sources does not increase that risk. It is important to stay within the recommended dosage range.

# Investigations: (PARIKSHAN)

Blood Tests, X-Ray, Bone Density Scan (DXA), M R I

# Pathogenesis: (SAMPRAPTI)

The plasma level of calcium is should be regulated with a normal total calcium of 2.2-2.6 mmol/L (9-10.5 mg/dL) and a normal ionized calcium of 1.1-1.4 mmol/L (4.5-5.6 mg/dL).

Calcium (Serum)	8.5 - 10.3 mg/dL Alt: 0-6 months: 8.9-11.0 mg/dL 7 mon to adults: 8.5-10.6	2.12 - 2.57 mmol/L
	mg/Dl	
Calcium (Urine)	Male: <300 mg/day Female: <250 mg/day	Male: <7.5 mmol/day Female: <6.2 mmol/day
Calcium (Ionized) Serum	4.5 - 5.6 mg/dL	Birth up to 1 month: 1.10-1.35 mmol/L 1 month-adult: 1.11 - 1.30 mmol/L
Vitamin D (1,25-Dihydroxy- vitamin D)(serum)	24 - 65 pg/mL	58 - 156 pmol/L
25-Hydroxyvitamin Vit D	10 - 55 ng/mL	25 - 137 nmol/L

## Prevention: (NIDAN PARIVARJAN)

Calcium deficiency can be prevented by adopting lifestyle changes that include eating a healthy diet and exercising.

More than most conditions, treating calcium deficiency require a significant amount of real effort on the person's part.

In addition, many studies have shown that certain oral Ayurvedic calcium medications may play a role in preventing calcium deficiency for people who are at the risk of it.

Lifestyle changes and medications may prevent approximately 40% to 80% of calcium deficiency.

This prevents the symptoms of calcium deficiency and the long-term complications of the condition.

## TREATMENT: CHIKITSA

Ayurvedic Medications are very effective at treating Calcium deficiency, reducing the symptoms and long-term effects of the bone condition.

#### Ayurvedic treatment: (CHIKITSA)

Apart from various drugs available in Ayurved we have selected a patented Ayurvedic herbal medicine named "CALCI V", manufactured by "Veer Health Care", Ahmedabad, India.

# Drug review: (AUSHADHI VIVECHAN)

Contains of CALCI V TABLET:

Each 500 mg of CALCI V Tablet contains:

Godanti Bhasma	:	113.50 mg	ASS	
Haad Sankal (Cissus quadrangularis)	:	151.50 mg	AB	LEAVES
Shallaki (Boswellia Serrata)	:	113.50 mg	AB	RESIN
Shu.Guggulu (Commiphora Wightii)	:	113.50 mg	AB	Exudate
Mari (Piper Naigrum)	:	8.00 mg	AB	Fruit
Excipients	:	q.s.		

Hindi	Weight	Botanical	Properties
Name		Name	
Godanti Bhasma	113.50 mg		<i>Godanti Bhasm</i> a is a Natural Remedy as a tonic for curing arthritis, diabetes and high cholesterol. A rich source of natural mineral Calcium.
Haad Sankal	151.50 mg	Cissus quadrangularis	It is a succulent vine from Africa and Asia. It is one of the most commonly used in traditional African and Ayurvedic medicine. All parts of the plant are used for medicine. It is used for bone fractures, weak bones (osteoporosis), scurvy, painful menstrual periods, and pain, body building supplement.
Shallaki	113.50 mg	Boswellia Serrata	Shallaki has b-boswellic acid. It is used in osteoarthritis, juvenile rheumatoid arthritis, soft tissue fibrositis and spondylitis. osteoarthritis, gout, joint pain, skeletal muscle pain and back pain. Inflammatory resistance and the healthy support of flexible joints.
Shu. Guggulu	113.50 mg	Commiphora Wightii	The plant has been used in traditional Ayurvedic medicine for centuries in the treatment of a variety of disorders, most notably arthritis, and as a weight- reducing agent in obesity. Other traditional uses have included treatment of liver problems, tumors, ulcers and sores, urinary complaints, intestinal worms, rheumatism ,arthritis, bone density
Mari	8 mg	Piper Naigrum	Kali mirch serves as a good source of dietary fiber, Vitamin K, promotes healthy cell growth and supports your skeletal health. Manganese and copper in it contribute to the health of your cartilage and bone tissue, and copper also promotes nervous system health

# Method:

The clinical study was planned by VAIDYA VINOD C MEHTA, BAMS (MUMBAI UNI) and DR MANAN V MEHTA, MBBS (MUMBAI UNI), in and around Mumbai and Ahmedabad.

## Plan of Study:

The study was planned by the doctors and volunteers to evaluate the clinical efficacy of "CALCI V" Tablet in the management of calcium.

## Inclusion criteria:

Above 18 years.

## **Exclusion criteria:**

Patients with severe dehydration, Toxic symptoms, sub or unconscious, Renal failure, severe hypoglycaemia.

## Study procedure:

Total 54 patients were selected for the study.

Each patient's complete medical history including personal data, a description of symptoms was taken. All the patients underwent a thorough clinical and pathological examination.

#### **GENDER:**

Male	24
Female	30
Total	54



20 to 30	7
30 to 40	12
40 to 50	26
50 to 60	9
Total	54



## **SYMPTOMS**

SYMPTOMS	NO OF PERSONS	%
OSTEOPENEA	17	31.48 %
JOINT PAIN	20	37 %
OSTEOPOROSIS	15	27.77 %
NUMBNESS	9	17.64 %
CRAMPS	9	17.64 %
WEAKNESS	26	48 %
ARTHRITIS	7	12.9 %
TOTAL	54	



## Dosage:

2 tablets of "CALCI V" were given to every one 2 times a day with water, after Lunch and After Dinner.

# Health Plan: (VIHAR)

- Walking
- Sun bath
- Swimming
- Regular exercise
- Increased water intake
- Proper meal timings
- Proper sleep

## (AHAR): To have: (PATHYA)

Three things were explained to patients.

- What they eat
- How much they eat
- When they eat
- A diet plan was tailored according to patients diet habit, working condition, daily routine, weight, age and gender.
- At above there are foods rich in calcium, such as Milk products, grains, fruit and vegetables, Fibre, Dark green leafy vegetables was suggested.

### Assessment of result: (UPSHAY)

After administration of CALCI V for 90 days, the following result was achieved.

SYMPTOMS		
SYMPTOMS	NO OF PERSONS	DECREASED %
OSTEOPENEA	3/17	82.35 %
JOINT PAIN	4 / 20	75 %
OSTEOPOROSIS	1 /15	93.33 %
NUMBNESS	0/9	100 %
CRAMPS	2/9	77.77%
WEAKNESS	8 / 26	69.23 %
ARTHRITIS	20 / 54	62.96 %



GOOD CONTROL	34	62.96 %
AVERAGE CONTROL	10	18.51 %
NOT IMPROVED	10	18.51 %
Total	54	100 %



# **Conclusion:**

According to result data it is established that "CALCI V"  $\,$ 

Is effective in curing symptoms of Calcium deficiency complications in 63 % of patients, shown average control in 18 % and was not found effective in 18 %.