

## Study Protocol

### Pharmaceutical Development, Quality Control Assessment and Comparative Evaluation of Efficacy of a Polyherbal Compound for Muscle Gain in Gym Going Healthy Volunteers: A Study Protocol

#### **Abstract**

**Introduction:** Protein powders are of great benefits for the youngsters who are gym freak and show an interest in bodybuilding need some external supplementation for weight gain, in muscle growth. In Ayurveda several herbs are described which are useful in muscle gain. Large number of protein supplements are available in market, but in present times research based *Ayurvedic* herbal supplement which is having dual property like muscle strengthening and other side as a protein source is not yet available in market. **Aim and objective:** Pharmaceutical Development, Quality Control Assessment and Comparative Evaluation of Efficacy of a Polyherbal Compound for Muscle Gain in Gym Going Healthy Volunteers. **Materials and methods:** Polyherbal compound will be prepared with selected drugs like *Ashwagandha*, *Vidarikanda*, *Arjuna*, *Gokshur*, *Sita* and it will be converted into churna form. Analytical study for standardization of Polyherbal compound will be done. Clinical evaluation for efficacy will be done in gym going healthy volunteers. **Observations and results:** Observation will be done on the basis of physical examination (assessment criteria) evaluation of the pre and post condition. Results will be drawn on the basis of observations and applying suitable tests. It will be noted and presented in form of table, charts, graph etc. **Conclusion:** If this Pharmaceutical preparation of Herbal Compound shows expected and significant outcome in muscle growth and then it will be boon to the youngsters, bodybuilders who are in search of such *Ayurvedic* muscle gain formulation.

**Key words:** Polyherbal compound, Muscle Gain, Gym, Healthy Volunteers

## Introduction

Ayurveda is the science of life, which deals with each and every aspect of life. Ayurveda places an emphasis on prevention and promotes health balance by emphasizing balance in lifestyle, nutrition, good thinking and the use of therapeutic herbs. Ayurveda knowledge aids in understanding how to achieve this balance of consciousness, mind and body according to their body constituents and preserve the improvements through lifestyle adjustments [1]. Everyone has a distinct fingerprint, and each person has a distinct pattern of energy. The combinations of emotional, mental and physical elements that make up a person's personality are reflected in their constitution. The constitution is already set by a number of elements at the moments of conception and remains the same throughout life [2]. Now a day's all youngsters are gym freak. They work hard to develop and sustain a lean, strong and well-defined physique and want some external supplementation for weight gain, in muscle growth[3].

Ayurveda has been with us for a very long time and has many advantages to shower on people. Ayurveda provides considerably safe and legal options to improve endurance, build muscle mass, body strength and increase physical stamina naturally [4]. Ayurvedic supplements benefits are likely stable and not decreasing even after discontinuing them[5]. Protein powder is a widely used dietary supplement. Protein is a necessary macronutrient for tissue repair, muscle growth, weight gain and the production of hormones and enzymes. Protein powders are of great benefits for the people who have an interest in bodybuilding or even people who want to lose weight and expecting muscle tone [6].

In Ayurveda several herbs are described which are useful in muscle gain. Several researches conducted on single drugs like *Ashwagandha*, *Musali* etc. have proven their muscle gain activity[7]. *Research on Withaniasomnifera and Terminaliaarjuna revealed that Ashwagandha is effective in generalized weakness and to improve speed and lower limb muscular strength and neuro-muscular co-ordination while Terminaliaarjuna is effective in*

improving cardio-vascular endurance and lowering systolic blood pressure [8]. *Tribulusterrestris* also called as puncture vine commonly used in most of the Ayurvedic medicines that have become a popular bodybuilding supplement [9]. Ginseng is one of the most studied herb for human physical performance and popular herbal dietary supplements worldwide [10]. term ginseng usually refers to the species *Panax ginseng*. Ginseng is available in many forms: whole root, rootpowder, steamed root powder, teas, tinctures and standardized root extracts [11].

*Ayurveda* holds the concept of *Brinhana* for overall growth of the body and potentiating the strength, energy and stamina in the healthy individuals. Despite their long tradition of use by a physically active person herbs have seldom been studied for scientifically as possible aid to physical performance. Except for the few studies still there is a dearth of scientific studies on the effect on herbs and herbal extracts on human physical performance. Generally athletes, sport persons, wrestlers consume herbs to enhance their long-term endurance performance. Hence in the present study attempt is made to generate scientific evidence of herbal compound as ergogenic aids for youngsters to enhance the physical strength and performance who exercise [12].

#### **Need of the study:**

Large number of protein supplements are available in the market, but in present times research based *Ayurvedic* herbal supplement which is having dual property like muscle strengthening and other side as a protein source is not yet available in the market. Protein supplement plays major role in weight gain and muscle growth and recovery. There is no information available regarding Ayurveda compound herbal supplement having this dual property. Hence there is a strong need to develop such a herbal compound.

#### **Aim and Objectives of Study:**

**Aim:** Pharmaceutical Development, Quality Control Assessment and Comparative Evaluation of Efficacy of a Polyherbal Compound for Muscle Gain in Gym Going Healthy Volunteers

#### **Objectives:**

1. To develop the SOP of Ayurvedic Polyherbal Compound.
2. To access the quality control parameters of Polyherbal Compound.

3. To compare the efficacy of Polyherbal compound with standard protein compound (Muscleblaze Super Gainer).
4. To evaluate the efficacy of Polyherbal compound in Muscle growth & BMI in gym going healthy volunteers.

**Materials and Methods:** Present work will be conducted under following headings.

### Pharmaceutical Study

This study is related to drug preparation in which three different batches of Polyherbal compound will be prepared to establish pharmaceutical standardization. Pharmaceutical study will be done in following steps;

- **Procurement of Raw materials:** All required raw materials will be procured from field and authentic reliable sources.

#### Drug collection and authentication:

- The research drug *Ashwagandha*, *Gokshur*, *Arjuna*, *Vidarikanda* will be procured from reliable source.
- Sugar Candy will be purchased from authenticated vender.
- Authentication of drugs will be done by Taxonomist /Dravyaguna department.
- Raw drugs will be standardized as per API or Analytical labs as MGACH and RC, and Central Research Lab of Jawaharlal Nehru Medical College, Sawangi (M) Wardha.
- According to need, study will be carried out at certified or standard institute/organization/ lab of national repute and as recognized or recommended by DMIMS (DU).

Table 1. Ingredients and quantity of Polyherbal Compound

S.N.	Ingredients	Part Used	Quantity
1	<i>Ashwagandha</i> ( <i>Withania somnifera</i> , Linn. Dunal)	Root	1 part
2	<i>Gokshur</i> ( <i>Tribulus terrestris</i> Linn)	Whole plant	1 part
3	<i>Vidarikanda</i> ( <i>Pueraria tuberosa</i> DC)	Tuber	1 part
4	<i>Arjuna</i> ( <i>Terminalia arjuna</i> W. & A.)	Bark	1 part

5	Sita (Sugar Candy)	-	1 part
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## Method

1. Preparation of Polyherbal Compound- polyherbal compound will be prepared as per churna Kalpana as described in Ayurveda[13]

### Flow diagram 1: Preparation of Polyherbal Compound(PHC)

All raw drugs (*Ashwagandha*, *Gokshur*, *Arjuna*, *Vidarikanda*) will be taken in equal quantity.

They will be triturated in grinder separately and sieved through 80 no. mesh.

Fine powders of all drugs will be taken in equal proportion and mixed homogeneously except sugar

At last sugar is added and mixed thoroughly. The mixture is stored in air tight wide mouthed containers for further therapeutic use

## Analytical Study:[14]

### Organoleptic:

- Odour
- Taste
- Touch
- Appearance

### Physico chemical analysis:

- Moisture analysis
- Particle size
- Total ash
- pH
- Acid-insoluble ash

- Water soluble / Alcohol soluble extractives
- Loss on drying at 105° c
- Microbial contamination
- Test for heavy metals

#### **Modern sophisticated analysis:**

1. HPTLC
2. GC- MS
3. Particle size distribution

- **Place of work:**

MGAC and RC, Salod (H), Wardha.

Health Club, DMIMS DU Campus, Sawangi, Meghe, (Wardha).

- **Study type-** Pharmaceutical Analytical and Interventional Study.
- **Study design:** Randomised standard control clinical trial (RCT).

#### **Selection of volunteer / Screening**

After a physical examination and complete blood count (CBC), FBS, LFT, RFT, T3 T4 TSH, Lipid Profile, and blood pressure with normal values, volunteers aged 20 to 30 years old will be chosen.

#### **Inclusion criteria**

1. Volunteers of age group between 20 to 30 years.
2. Haematological and biochemistry reports within normal range.
3. Volunteers willing to participate and giving written consent.
4. BMI within normal range 18-24.
5. Waist - Hip Circumference within 83-98cm.
6. Mid - Arm Circumference within 23cm to 25.5cm.
7. Muscular Strength (Leg press 1RM & Bench press 1 RM) [15]

#### **Exclusion criteria**

1. Volunteers below 20 years & above 30 year of age.

2. Volunteers with any medication or having any major systemic disorder will be excluded.
3. History of drug, smoking or alcohol abuse.
4. On any medication or supplement during the past 6 months Pulmonary disease, Dyslipidaemia, Cardiovascular disease, Liver or renal disease, Skeletal damage, hypertension, Lactose intolerance and Diabetes. They should not have done any previous regular gym training or were not under any special diet.
5. Volunteers who are not willing to participate and giving written consent.

**Table No 2: Dosing schedule**

Group	Group Code	Supplements	Dose	Adjuvant	Duration	Follow-up	Participant
Trial group	HC	Polyherbal Compound	12 gm	Cow's milk (At evening)	6 weeks	After 15 <sup>th</sup> Day, 30 <sup>th</sup> Day, 45 <sup>th</sup> Day of drug Administration	30
Standard control	PS	Standard Protein Supplement. (Muscleblaze)	12gm	Cow's milk (At evening)	6 weeks	After 15 <sup>th</sup> Day, 30 <sup>th</sup> Day, 45 <sup>th</sup> Day of drug Administration	30

**Sample Size:**

To find out therapeutic potential of this Polyherbal compound the study will be conducted on 60 volunteers (30 in each group).

**Methodology**

The volunteers will be informed about the study protocol. Willing participants will be randomly selected as per computer generated table. Clinical research format will be prepared and validated. Prior to the study approval will be taken from IEC, MGACHRC, Salod (H) Wardha and CTRI registration will be done. After selection, each participant will be tested individually and selected according to selection criteria. They are divided into two groups. In one group (30 participants) we will give Muscleblaze (muscle toner) as a standard drug and other group (30

participants) will receive Polyherbal compound for 6 weeks with day wise schedule of exercises. Dose will be 12 gm each with cow's milk advised to be taken at evening. Before and after treatment photographic evaluation will be done. After inclusion in study protocol each participant will receive the respective treatment from day one for 6 weeks. A container of 1kg Polyherbal compound will be given to them. Instruction regarding to consumption will be given to each participant. Telephonic reminder will be given for taking the dose timely. In person follow up will be taken on 15th, 30th and 45<sup>th</sup> day. After completing the treatment for 6 weeks, each participant will be evaluated using Ayurvedic and modern parameters. Individuals, who will miss even 1 application of drug in total 45 days, will be dropped out from the clinical study. Post treatment follow up will be taken for next 6 weeks.

**Table No 3: Training protocol for experimental group[9]**

Main Goal	Muscle Building
Training Level	Intermediate
Days for workout	7 days
Workout Time	60 Min/day
Equipment	Dumbbell, Body weight, EZ bar, Barbell, Cables, Machines.

**Table No 4: Day 1, 2- Lower body (Hamstring & Glute Focused) [9]**

EXERCISE	SETS	REPS
Dead lifts ( single leg & Romanian)	2	6-8
Squats	2	6-8
Leg curl	2	6-8
Donkey Kick	2	6-8
Dumbbell swing	2	6-8
Lung back kick	2	6-8
Bulgarian Split Squat	2	6-8
Weighted Glute bridges	2	6-8
Alternate Crusty lungs	2	6-8
Sumo Dumbbell Squats	2	6-8

**Table No. 5: Day 3, 4 – Upper Body (Push Focused)**

<b>EXERCISE</b>	<b>SETS</b>	<b>REPS</b>
Incline Dumbbell Press	2	6-8
Push Up	2	6-8
Front Raise	2	6-8
Seated Dumbbell Press	2	6-8
Hammer Curls	2	6-8
One Arm Row	2	6-8

**Table No.6: Day 5, 6-Lower Body (Quad & Calf Focused)**

<b>EXERCISE</b>	<b>SETS</b>	<b>REPS</b>
Squat	2	6-8
Dumbbell Lung	2	6-8
Leg press	2	6-8
Leg Extension	2	6-8
Seated Calf Raise	2	6-8

**Table No 7: Day 7- Upper Body (Pull Focused)**

<b>EXERCISE</b>	<b>SETS</b>	<b>REPS</b>
Bent Over Row	2	6-8
Seated Cable row	2	6-8
Lat Pull Down	2	6-8
Standing Cable Reverse Fly	2	6-8
Barbell Curl	2	6-8
Reverse Dumbbell Curl	2	6-8

**Assessment Criteria**

## Biochemical parameters

### Screening parameters

- Complete blood count
- Lipid profile
- LFT , RFT
- TSH, T<sub>3</sub> , T<sub>4</sub>
- FBS

### Assessment criteria: [16]

- Weight
  - Muscle power
  - BMI
  - Waist – hip circumference
  - Mid – arm circumference
  - Muscular strength ( Bench press, Leg press)
  - Skin fold thickness ( Measured by skinfold/ Vernier calliper's)
  - Hip – waist ratio
  - Sagittal diameter abdomen
  - Body fat percentage.
- Post assessment will be tabulated as under corresponding to the grades above, noted prior to treatment.

**Table No. 8: Gradation of overall result of the study**

A.	Highly Significant Muscle Growth	75-100% Gain
B.	Significant Growth	50-74% Gain
C.	Mild Improvement	49% Gain
D.	Unsatisfactory	<25% Improvement From Assessment

**Study Duration:** 2 years

**Administration of drug:** 6 weeks

### Observation

Observations will be noted and presented in the form of tables, charts, photographs etc.

## Discussion:

Present research focuses on the tenets of *BhaishajyaKalpanato* evaluate a new Polyherbal compound for muscle gain. The basic *Ayurvedic* principles of ease of availability (natural abundance), cost effectiveness, and easily consumable, keeping in consideration the demands of current lifestyle trends and youngster's preferences will be followed to provide a holistic remedial for weight gain, increasing muscle gain & strength, body tone, flexibility of body. The intended ingredients in the formulation are Ashwagandha, Vidarikanda, Arjuna, Gokshur and Suger. This formulation has been devised in accordance with the overarching guiding principles of *Ayurveda* that encourage individual preference and ease of preparation and consumption. The methodology of formulation and preparation will follow the procedures outlined in texts diligently [17]. Considering current lifestyle and trending preference amongst Youngster's a standardized formulation will be prepared. The churna form is easier to carry and consumption, and also has a better shelf life [18].

The efficacy of the drug will be tested by comparing the effect of the drug with standard drug with pre and post assessment in Muscle gain. The dosage and frequency will be suggested at the outset and following clinical assessment, the researcher expects to establish the efficacy, acceptability and outcome of the Polyherbal compound. Studies on efficacy of different Ayurvedic preparations were reported [19-21]. Few of the related studies were reviewed. There are many protein formulations of herbal origin available in the market. Research work also available on single drugs such as *Ashwangdha*, *Shatavari*, *Musali*, *Vidarikanda* to test the efficacy of muscle tone. But there is no any research work available on combination of drugs which are used as herbal supplement in gym going healthy volunteer. On literature search, few drugs have shown some characteristic features. *Gokshur* is having tremendous effect in decreasing exercise related fatigue [22-24], *Arjuna* is also found useful in gaining aerobic exercise capacity [8]. No such formulation is available and developed previously hence considering the actions of these drugs in enhancing the muscle tone and muscle strength new formulation is planned and its action sought in gym going healthy going volunteer.

**Conclusion:**

If this Pharmaceutical preparation of Herbal compound shows expected and significant outcome in muscle growth then youngsters, bodybuilders can be used research base *Ayurvedic* Herbal compound in day to day life. If this herbal compound found to be effective in enhancing human physical performance then it will open a new era for another such studies.

**Statistical Tests:**

Statistical analysis will be done by applying Pair and Unpaired "t" Test, One way ANOVA and suitable descriptive statistical tests.

**NOTE:**

**The study highlights the efficacy of " Ayurveda " which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.**

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