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Non-surgical Periodontal Therapy and Myo-inositol in Polycystic Ovary Syndrome Women Having Chronic Periodontitis

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Purpose

The Purpose of this study is to assess the correlation between the inflammatory periodontal status and the medical treatment status in Polycystic Ovary Syndrome(PCOS) women with systemic inflammation and to evaluate the effect of non-surgical periodontal therapy in the form of scaling and root planing along with medical treatment on the level of serological marker of inflammation (High sensitivity-C Reactive Protein) and insulin resistance in PCOS women with chronic periodontitis.

Status	Active, not recruiting
Condition	Polycystic Ovary Syndrome
Phase	Phase 2
Study Type	Interventional
Study Design	Allocation: Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Parallel Assignment, Masking: Single Blind (Outcomes Assessor), Primary Purpose: Treatment
Official Title	Effect of Non-surgical Periodontal Therapy Along With Myo-inositol on High Sensitivity C-reactive Protein and Insulin Resistance in Polycystic Ovary Syndrome Women Having Chronic Periodontitis: A Randomized Controlled Trial

Further study details (as provided by National Institutes of Health Clinical Center (CC))

Enrollment	56
Start Date	May 2015

Detailed Description

Polycystic Ovary Syndrome(PCOS) is a genetically complex endocrine disorder of uncertain etiology and a common cause of hyperandrogenism, anovulatory infertility, menstrual dysfunction, hirsutism, alopecia and acne. It was first reported by Stein and Leventhal in 1935. It affects 6-8% of women of

reproductive age. Accordingly PCOS might be viewed as a gender specific form of metabolic syndrome. According to Androgen Excess Society(AES) /2006 criteria PCOS was defined by the presence of hyperandrogenism (clinical and/or biochemical),Oligo or anovulation, Polycystic ovarian morphology(PCOM)- at least one ovary with 1)12 or more follicles (2-9 mm in diameter) or 2) Ovarian volume >10 ml. Patients with PCOS are at higher risk of developing cardiovascular risk factors that is diabetes, insulin resistance, visceral obesity and a state of low grade inflammation.Therefore, PCOS may represent a model for studying the complex interaction among these Cardiovascular risk factors,especially chronic inflammation and insulin resistance. Visceral obesity,insulin resistance and hyperinsulinemia are prevalent co-morbidities of PCOS which promotes androgen excess.Insulin resistance in PCOS is due to a post-receptor defect in insulin receptor mediated cells which leads to induce a decrease in glucose transporters. Therefore, reduction of insulin secretion and/or improvement of its action at target tissues offer the possibility of improving the effects of androgen excess by correction of the reproductive dysfunction and preventing metabolic derangements from becoming entrenched. For this purpose many insulin-sensitizing agents like metformin have been tried as a treatment modality of metabolic as well as reproductive dysfunction in PCOS.Myo-inositol (MI) is a naturally occurring substance produced in the human body that belongs to the vitamin B complex group.PCOS has been linked to a deficiency in myo-inositol. MI can be synthesized by the body from food, but when the investigators are already deficient, the lack of MI can impact the ability of the body to be sensitive to insulin. MI plays an important role as the structural basis for a number of secondary messengers including synthesis of phosphatidylinositol 3-kinase (PI 3-kinase), a key messenger to improve insulin sensitivity and thereby reducing insulin resistance Supplying extra MI appears to temporarily correct the impaired insulin pathways and reduce the signs and symptoms of insulin resistance. Periodontal diseases, including gingivitis are common chronic infectious diseases characterized by a gingival inflammatory response against predominantly pathogenic microorganisms that colonize the subgingival area and cause local and systemic elevations of proinflammatory cytokines, such as tumor necrosis factor-a and interleukin-6 resulting in loss of connective tissue attachment, alveolar bone resorption which can result in tooth loss. It is well established that patients suffering from periodontitis present with a low grade systemic inflammatory state when compared with healthy subjects.Increased concentrations of inflammatory biomarkers in both gingival tissues and serum such as C-reactive protein and interleukin have been reported. Periodontal disease has been implicated as risk factor in the onset and development of various cardiovascular diseases like diabetes mellitus cerebrovascular and coronary artery diseases.9,10,13 Chronic stimulation and secretion of proinflammatory cytokines associated with periodontal infection contribute to the insulin resistance in these patients. Insulin resistance syndromes such as type 2 diabetes mellitus and PCOS have been linked to slightly elevated serum C-reactive protein. As already being discussed,Periodontitis has also been linked to elevated CRP levels, therefore it is postulated that CRP might be a possible mediator of the association between periodontitis and systemic diseases1 Because of the fact that both periodontal disease and metabolic syndrome are associated with systemic inflammation and insulin resistance,these two disorders may be linked through a common pathophysiologic pathway. Earlier there have been many cross-sectional studies describing a possible relationship between PCOS and periodontitis and the impact of PCOS on gingival inflammation However, they have not taken into account the medical treatment status, duration or the type of treatment modality employed for the medical treatment of the syndrome. They also have not evaluated the effect of periodontal therapy on the periodontium, systemic inflammation and insulin resistance in PCOS women suffering with inflammatory periodontal disease. Therefore through this study, the investigators aim to assess the correlation between the inflammatory

periodontal status and the medical treatment status in PCOS patients with systemic inflammation and to evaluate the effect of non surgical periodontal therapy along with medical treatment on the level of serological marker of inflammation(High sensitivity-CRP) and insulin resistance. MATERIALS AND METHOD: This study will be conducted in department of Periodontics and Oral Implantology, Post Graduate Institute of Dental Sciences (PGIDS), Rohtak in collaboration with department of Obstetrics and Gynaecology, Post Graduate Institute of Medical Sciences (PGIMS), Rohtak STUDY POPULATION AND DESIGN: The study will be conducted as following: Patients (n=25 per group) for interventional study will be recruited from regular OPD(Out Patient Department) of the Dept. of Periodontology,Dept. of Obstetrics and Gynaecology and dept. of Oral Medicine. GROUP A: Systemically and periodontally healthy females (Age and BMI matched) also recruited from the department of oral medicine. INTERVENTIONAL STUDY An Randomized clinical trial will be done to evaluate the effect of Non-surgical periodontal therapy along with myoinositol on systemic inflammatory marker, insulin resistance, anthropometric and periodontal parameters in newly diagnosed patients of PCOS having periodontal disease. They are divided into following groups: Women having Polycystic ovarian syndrome(PCOS) and chronic periodontitis will be randomly divided into two groups: Test Group: Polycystic ovarian syndrome(PCOS) women who have periodontitis and treated with scaling and root planing along with Myo-inositol supplementation(1 gm twice a day) Control Group: Polycystic ovarian syndrome (PCOS) women who have periodontitis treated with Myo-inositol (1 gm twice a day)along with oral hygiene instructions INCLUSION CRITERIA: - Females of reproductive age group (15-35 yrs) - Subjects diagnosed with PCOS according to Androgen Excess Society(AES)/2006 criteria: - Presence of hyperandrogenism (clinical and/or biochemical) - Oligo or anovulation - PCOM (Polycystic ovarian morphology)- at least one ovary with 1)12 or more follicles (2-9 mm in diameter) or 2) Ovarian volume >10 ml - Presence of ≥20 natural teeth - Patients having Chronic Periodontitis will be defined according to division of Oral Health at the Centers for Disease Control and Prevention (CDC) in collaboration with American Academy of Periodontology (AAP) Moderate periodontitis: ≥ 2 interproximal sites with AL, ≥4 mm (not on same tooth), or ≥2 interproximal sites with PD ≥5 mm (not on same tooth) (Page and Eke 2007) EXCLUSION CRITERIA - Any history of thyroid dysfunction, hyperprolactinemia, androgen - secreting tumour, nephrotic syndrome, chronic renal failure. - Significant cardiovascular disease. - Established type 1 or type 2 diabetes mellitus. - Active cancer within the last past 5 yrs. - Smokers and alcoholic subjects. - History of systemic antibiotics or oral contraceptives usage within last 3 months. - Periodontal treatment within 6 months prior to study Prior informed consent will be taken from each patient after explaining the procedure along with the risks and benefits in their own language. All the subjects in the study will undergo the examination of the various anthropometric, metabolic and periodontal parameters and ultrasonography. Anthropometric and Metabolic parameters will be re-evaluated at a recall period of 6 months. ANTHROPOMETRIC PARAMETERS - Waist circumference - Waist and hip ratio - Body mass index METABOLIC PARAMETERS - Serum (Follicle Stimulating Harmone)FSH/(Leutinising Harmone)LH - Fasting Blood sugar - Serum testosterone - Serum Prolactin - Lipid profile - Serum hsCRP - Fasting Insulin Parameter for insulin resistance - Homeostatic Model Assessment(HOMA) for insulin resistance(IR) It is the product of the fasting values of glucose(expressed as mg/dl) and insulin expressed as μU/ml (micron unit/millilitre) is divided by a constant: Insulin×Glucose/405 The constant 405 should be replaced by 22.5 if glucose is expressed in Standard International(SI) units(mmol/l) Sample for the metabolic parameters will be collected on the second or third day of the menstrual cycle. PERIODONTAL PARAMETERS - Plaque index (PI)(Silness & Loe) - Gingival index (GI)(Loe & Silness) - Bleeding on probing (BOP) - Pocket depth (PD) - Clinical attachment level (CAL) Each of the tooth will be assessed at six sites(mesio-buccal, mid-buccal, disto-

buccal, mesio-lingual/palatal, mid-lingual/palatal and disto-lingual/palatal) for Bleeding on probing, Pocket depth and Clinical attachment level and at four sites(mesio-buccal, mid-buccal, disto-buccal and mid-lingual/palatal) for plaque index and gingival index during full mouth complete periodontal examination.Periodontal parameters will be evaluated at 3 and 6 months. Processing Of Data: Data recorded will be processed by standard statistical analysis.

Eligibility

Minimum Age Eligible for Study:	15 Years
Maximum Age Eligible for Study:	35 Years
Genders Eligible for Study:	Female

Criteria

Inclusion Criteria: - Females of reproductive age group (15-35 yrs) - Subjects diagnosed with PCOS according to AES (Androgen Excess Society)/2006 criteria: - Presence of hyperandrogenism (clinical and/or biochemical) - Oligo or anovulation - PCOM (Polycystic ovarian morphology)- at least one ovary with 1)12 or more follicles (2-9 mm in diameter) or 2) Ovarian volume >10 ml - Presence of ≥20 natural teeth - Patients having Chronic Periodontitis will be defined according to division of Oral Health at the Centers for Disease Control and Prevention (CDC) in collaboration with American Academy of Periodontology (AAP) Moderate periodontitis: ≥ 2 interproximal sites with AL, ≥4 mm (not on same tooth), or ≥2 interproximal sites with PD ≥5 mm (not on same tooth) (Page and Eke 2007) Exclusion Criteria: Any history of thyroid dysfunction, hyperprolactinemia, androgen -secreting tumour, nephrotic syndrome, chronic renal failure. - Significant cardiovascular disease. - Established type 1 or type 2 diabetes mellitus. - Active cancer within the last past 5 yrs. - Smokers and alcoholic subjects. - History of systemic antibiotics or oral contraceptives usage within last 3 months. - Periodontal treatment within 6 months prior to study

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT02633462

Locations

Sponsors and Collaborators

Postgraduate Institute of Dental Sciences Rohtak

More Information

Other Publications

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