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THINK TWICE BEFORE YOU GULP ORAL CONTRACEPTIVES

Neethu Fathima Umar*

Contraceptives are used widely among the women all over the world. As per the survey conducted by WHO in 2015, 64% of married or in-union women of reproductive age worldwide were using some form of contraception. At least one in ten married women in most regions of the world has an unmet need for family planning. The survey estimated that nearly 800 million married or in-union women would be using contraception by 2030.

Apart from the need for controlling unwanted child births, adolescent girls and young women are often prescribed birth control pills for irregular menstrual cycles, menstrual cramps, acne, premenstrual syndrome, endometriosis, primary ovarian insufficiency and for polycystic ovary syndrome (PCOS). Girls who are diagnosed with PCOS are often prescribed oral contraceptives to lower their hormone levels and regulate their menstrual periods. Birth control pills contain one or two types of synthetic female hormones, oestrogen and progestin. The ovaries normally make similar hormones, naturally occurring oestrogen and progesterone have been found to influence the growth and development of certain cancers.

Since birth control pills contain female hormones, researchers have been interested in investigating any link between these widely used contraceptives and cancer risk. The results obtained from population studies to examine associations between oral contraceptive use and cancer risk have not been consistent. The risks of endometrial and ovarian cancer has been found to be reduced with the use of oral contraceptives on the other hand the risks of breast, cervical, and was found to be increased.

A woman's risk of developing breast cancer depends on several factors. Hormonal and reproductive history factors that increase the risk of breast cancer include

- Onset of menstruation at an early age
- Onset of menopause at a late age
- Later age at first pregnancy
- Staying nullipara (not having children at all)

A 1996 analysis of epidemiologic data from more than 50 studies worldwide by the Collaborative Group on Hormonal Factors in Breast Cancer found that women who were current or recent users of birth control pills had a slightly higher risk of developing breast cancer than women who had never used the pill. The risk was highest for women who started using oral contraceptives as teenagers. However, 10 or more years after women stopped using oral contraceptives their risk of developing breast cancer had returned to the same level. As if they had never used birth control pills, regardless of family history of breast cancer, reproductive history, geographic area of residence, ethnic background, differences in study design, dose and type of hormone used or duration of use.

There are many different formulations of oral contraceptives; the most common are a combination of the estrogenic hormone ethinyl estradiol and synthetic progestin.

A 2014 study of female enrollees in a large U.S. integrated health care delivery system studied the formulation differences. This study reconfirmed that recent oral contraceptive use was associated with an increased breast cancer risk. Three specific formulations of oral contraceptives were associated with particularly elevated risks. These included high-dose oestrogen, ethinyl estradiol diacetate and triphasic dosing at an average of 0.75 mg. Other types including low-dose estrogen oral contraceptives were not associated with elevated risks. The risk for breast cancer is greatest among current and recent users, particularly those who have used them for more than five years and, especially, those who started using birth control pills earlier in life and took them for longer periods.

Women with BRCA1 or BRCA2 mutations as well as women with family history of breast or ovarian cancer have an increased susceptibility to the risk-inducing effects of oral contraceptive exposures. A recent study indicates that when the BRCA mutation comes from the father's genes it has greater risk for women with this genetic variation who also use oral contraceptives. One mechanism by which the interaction between BRCA gene status and use of oral contraceptives may influence breast cancer risk is alteration of the sensitivity and activity of progesterone in breast cancer cells by increasing the synthesis of progesterone receptor (PR) in the cells and by enhancing the responsiveness of progesterone-regulated genes.

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PSYCHOTROPIC DRUGS AND HEART

Dr. Juno J. Joel*

Quite a lot of studies have established higher rates of cardiovascular death among psychiatric patients, predominantly those with schizophrenia, compared with the general population[1]. Reports of unexpected deaths of children and adolescents treated with psychotropic medications have raised concerns regarding the appropriateness of this therapy, as well as the advisability of baseline and periodic electrocardiographic (ECG) monitoring of such patients[2,3].

Cardiac risk factors, including smoking, lack of exercise, obesity, substance-misuse and high autonomic arousal during physical restraint are over represented in psychiatric patients. As the psychotropic medications are prescribed for the risk population, it becomes necessary to consider its cardiovascular effects.

Possible Mechanisms for Sudden Death

Although medications can potentially cause sudden, unexpected death by a variety of mechanisms (eg, seizures, central nervous system depression, or coronary artery spasm), cardiac arrhythmias are the most frequent cause. In particular, a unique form of ventricular tachycardia termed torsade de pointes has been recognized as the arrhythmia responsible for the so-called proarrhythmic effect of several antiarrhythmic drugs, and recent evidence has pointed to a similar mechanism in syncope and deaths related to other medications[4] and in the familial long-QT syndromes.[5] The common feature of these conditions is delayed repolarization of the myocardium (related to abnormal sodium or potassium currents) with resultant prolongation of the QT interval of the ECG. This appears to leave the myocardium vulnerable to ventricular tachycardia, primarily in the setting of bradycardia but occasionally in association with exercise. Other ECG abnormalities, such as sinus node depression, second- or third-degree heart block, and supraventricular tachycardia, seem unlikely causes of sudden death in patients receiving psychotropic medications.

Specific Drugs

Thioridazine, an old and widely prescribed neuroleptic drug that was recently withdrawn, was associated with 75% of 49 deaths in a patient group taking a single antipsychotic drug regimen; its potential for QT prolongation had already been reported in 1963.[6,7] Unexplained sudden death in young adults has been linked to the prescription of antipsychotics other than thioridazine.[8]

Stimulants such as the amphetamines and methylphenidate cause slight but clinically insignificant increases in heart rate and blood pressure. The tricyclic antidepressants (TCA) imipramine and desipramine have been associated with at least 7 reported deaths in young patients.[2,9] The precise mechanism of death has not been documented.

Drug Interactions

Many psychotropic medications are metabolized by the cytochrome P450 system, an enzyme system that may be inhibited by a multitude of medications[10]. Adverse effects have occurred when the P450 system is inhibited, which leads to elevated levels of medications that prolong the QT interval and produce ventricular tachycardia (torsade de pointes). Most notable have been deaths related to torsade de pointes from non-sedating histamine-blocking agents such as terfenadine and astemizole.[11] Other classes of medications that inhibit or are metabolized by the P450 cytochrome system include antidepressants, calcium channel blockers, histamine blockers, gastrointestinal motility agents, and steroids. Prolongation of the QT interval and torsade de pointes have been reported in young children taking cisapride. Antiarrhythmic drugs of class Ia (eg, disopyramide, procainamide, and quinidine) and class III (eg, amiodarone and sotalol) likewise prolong the QT interval, and therefore concomitant use of psychotropic medications with these drugs is not recommended[12].

Family History

In some families, syncope and sudden death have been related to familial prolongation of the QT interval and torsade de pointes. Such individuals are at increased risk for arrhythmias due to medications that prolong the QT interval. Drugs that prolong the QT interval are contraindicated in patients with familial long-QT syndrome[12].

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A REVIEW ON CANCER VACCINE

Anila Varkey*

Cancer has become one of the most devastating diseases worldwide. More than 575,000 people die of cancer, and more than 1.5 million people are diagnosed with cancer every year. The WHO has predicted this figure to be 15 million per year by 2020. The aim of cancer vaccines is to stimulate the immune system to be able to recognize cancer cells as abnormal and destroy them. Some vaccines for particular cancers have been developed and are being tested to see whether they can treat a cancer, or help to stop it from coming back after cancer treatment.

Currently several techniques are being used to treat cancer. In the present scenario, scientists are on the verge of developing cancer vaccines that will save millions of lives annually when it is discovered. Cancer vaccines are medicines that belong to a class of substances known as Biological response modifiers, which works by stimulating, or restoring the immune system's ability to fight infections, Cancer causing viruses, treats existing cancer or prevents the development of cancer in certain high-risk individuals.

Table 1: Type of Cancer Vaccines

Types of vaccine	Description
Preventive (or prophylactic) vaccines	Prevent the cause of cancer from developing in healthy people
Treatment (or therapeutic) vaccines	Treat an existing cancer by strengthening the body's natural defences mechanisms against the cancer

Table 2: List of Cancer Vaccines being developed

Vaccine type	Description
Antigen vaccines	Tumor specific antigen protein
Tumor cell vaccines	Have antigens to mount to an effective anti tumor response
Dendritic cell vaccines	it breaks the cancer cell surface into small pieces
Anti-idiotype vaccines	They will produce anti-idiotype antibodies to attack the idiotype
DNA vaccines	Bits of DNA from the patient's cells are injected into the patient so other cell produce certain antigens.

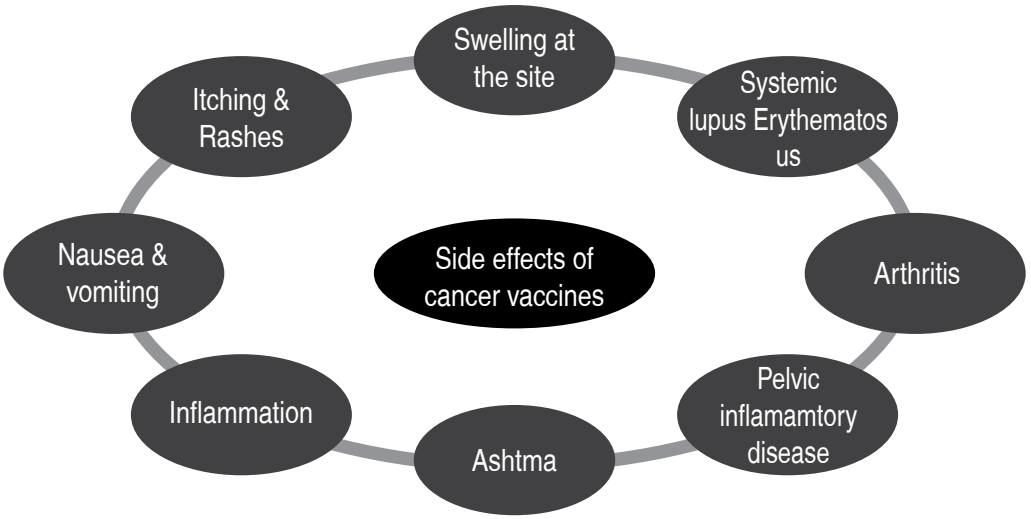

Figure 1: Side effects of cancer vaccines

Future Cancer Vaccines:

The discovery of cancer vaccines is going on fast pace. There are number of cancer vaccines undergoing clinical trials. Here is the list of companies and their vaccines in development

1. Dendreon Corp (DNDN) -Neuvenge, for HER2/neu expressing cancers such as Breast, Bladder, colon, Ovarian.
2. Celldex Therapeutics- CDX110, CDX1307 and CDX1401.
3. Heat Biologics- ImPACT Therapy against NSCLC and other cancers.
4. Geron Corporation- GRNVAC1.
5. BN ImmunoTherapeutics - PROSTVAC.
6. Globe Immune –Tarmogens, GI-4000.
7. Advaxis - ADXS11-001, ADXS31-001, ADXS31-164.
8. Accentia Biopharmaceuticals majority owned subsidiary Biovest International-BiovaxID.
9. GeneMax Corp- GMXX.
10. Apthera, Inc. –NeuVax.
11. Avax Technologies -AC Vaccine.
12. Generex Biotechnology through its wholly owned immunotherapeutic subsidiary Antigen Express (Ae-37).
13. Immatics biotechnologies - IMA901 for renal cancer
14. Scancell Holdings-SCIB1.
15. Merck - in 2009, starting phase III trials of Stimuvax for breast cancer. It had promising results from a phase IIB trial for inoperable lung cancer.
16. Oncotherapy Science - The first world peptide vaccines are produced. Some of vaccines are now in phase II & III.

Conclusion

Cancer vaccines represent an emerging type of biological therapy that is still mostly experimental. Many clinical trials are underway to test vaccines as potential treatments for a wide variety of cancer types. Possibly the most exciting achievement of this century will be the discovery of a universal cancer vaccine. The various types of cancer vaccines and their clinical trials are most satisfactory, which giving energy to the scientific community to concentrate more in this area. Future progress and development in this area surely provide the human kind beautiful weapons to fight with all kinds of cancer

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NEW DRUGS APPROVED BY U.S. FOOD AND DRUG ADMINISTRATION (FDA)
(JANUARY – JUNE 2016)

Dr. Uday Venkat Mateti*

Specialty	Drug Name	Brand Name	Company Name	Uses	Approved (Month)
Cardiology/ Vascular Diseases	Nebivolol and valsartan	Byvalson	Allergan	Hypertension	June 2016
Dermatology	Ixekizumab	Taltz	Eli Lilly	Plaque Psoriasis	March 2016
	Aminolevulinic acid hydrochloride	Ameluz	Biofrontera Pharma	Actinic Keratosis	May 2016
Family Medicine	Sumatriptan nasal powder	Onzetra Xsail	Avanir	Migraine	January 2016
	Nebivolol and valsartan	Byvalson	Allergan	Hypertension	June 2016
Hematology	Coagulation Factor IX (Recombinant), Albumin Fusion Protein	Idelvion	CSL Behring	Hemophilia B	March 2016
	Antihemophilic Factor (Recombinant)	Kovaltry	Bayer	Hemophillia A	March 2016
	Venetoclax	Venclexta	AbbVie	Chronic Lymphocytic Leukemia With 17p Deletion	April 2016
	Nivolumab	Opdivo	Bristol-Myers Squibb	Classical Hodgkin Lymphoma	May 2016
	Antihemophilic Factor Recombinant, Single Chain	Afstyla	CSL Behring	Hemophillia A	May 2016
Hepatology (Liver, ancreatic, Gall Bladder)	Elbasvir and grazoprevir	Zepatier	Merck	Chronic HCV genotypes 1 or 4	January 2016
	Defibrotide Sodium	Defitelio	Jazz Pharmaceuticals	Hepatic veno-occlusive disease with renal or pulmonary dysfunction following HSCT	March 2016
	Obeticholic acid	Ocaliva	Intercept Pharmaceuticals	Primary biliary cholangitis	May 2016
Urology	Atezolizumab	Tecentriq	Genentech	Urothelial carcinoma	May 2016

Pulmonary/ Respiratory Diseases	Reslizumab	Cinqair	Teva Pharmaceuticals	Severe asthma	March 2016
	Glycopyrrolate and formoterol fumarate	Bevespi Aerosphere	AstraZeneca	Chronic obstructive pulmonary disease	April 2016
Psychiatry/ Psychology	Pimavanserin	Nuplazid	Acadia Pharmaceuticals	Hallucinations and delusions associated with Parkinson's disease psychosis	May 2016
Pediatrics/ Neonatology	Antihemophilic Factor (Recombinant)	Kovaltry	Bayer	Hemophillia A	March 2016
Nephrology	Cabozantinib	Cabometyx	Exelixis	Advanced renal cell carcinoma	April 2016
	Lenvatini	Lenvima	Eisai	Advanced renal cell carcinoma	May 2016
Oncology	Cabozantinib	Cabometyx	Exelixis	Advanced renal cell carcinoma	April 2016
	Venetoclax	Venclexta	AbbVie	Chronic lymphocytic leukemia with 17p deletion	April 2016
	Lenvatinib	Lenvima	Eisai	Advanced renal cell carcinoma	May 2016
	Nivolumab	Opdivo	Bristol-Myers Squibb	Classical Hodgkin lymphoma	May 2016
	Atezolizumab	Tecentriq	Genentech	Urothelial carcinoma	May 2016
Neurology	Sumatriptan nasal powder	Onzetra Xsail	Avanir	Migraine	January 2016
	Brivaracetam	Briviact	UCB	Partial onset seizures related to epilepsy	February 2016
	Pimavanserin	Nuplazid	Acadia Pharmaceuticals	Hallucinations and delusions associated with Parkinson's disease	April 2016
	Pimavanserin	Nuplazid	Acadia Pharmaceuticals	Hallucinations and delusions associated with Parkinson's disease psychosis	May 2016
Musculoskeletal	Daclizumab	Zinbryta	Biogen	Relapsing multiple sclerosis	May 2016
Infections and Infectious Diseases	Elbasvir and grazoprevir	Zepatier	Merck	Chronic HCV genotypes 1 or 4	January 2016
	Emtricitabine, Rilpivirine, and Tenofovir Alafenamide	Odefsey	Gilead Sciences	HIV-1 as initial therapy	March 2016
	Obiltoxaximab	Anthim	Elusys Therapeutics	Inhalational anthrax	March 2016
	Emtricitabine and Tenofovir Alafenamide	Descovy	Gilead	HIV-1 infection	April 2016
	Cholera Vaccine, Live, Oral	Vaxchora	PaxVax	Active immunization against Cholera	June 2016

Immunology	Ixekizumab	Taltz	Eli Lilly	Plaque psoriasis	March 2016
	Obiltoxaximab	Anthim	Elusys Therapeutics	Inhalational anthrax	March 2016
	Emtricitabine and Tenofovir alafenamide	Descovy	Gilead	HIV-1 infection	April 2016
	Antihemophilic Factor (Recombinant), Single Chain	Afstyla	CSL Behring	Hemophillia A	May 2016
	Cholera Vaccine, Live, Oral	Vaxchora	PaxVax	Active immunization against Cholera	June 2016

Reference: http://www.centerwatch.com/drug-information/fda-approved-drugs/. (Last accessed on June 30, 2016)

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NEW DRUGS APPROVED BY CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO), INDIA

(JANUARY – JUNE 2016)

Dr. Uday Venkat Mateti*

Drug Name	Strength	Indication	Date of issue
Nintedanib	100/150 mg soft Gelatin Capsule	Idiopathic Pulmonary Fibrosis (IPF)	11th March 2016
Cisatracurium Besylate	Bulk & 2mg/ml injection	As an adjunct to general anaesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery	14th March 2016
Fomepizole	Bulk &1.5gm/Ampoule	As an antidote for Ethylene glycol or Methanol used poisoning For use in suspected. Or Ethylene glycol or Methanol ingestion, either alone or in combination with hemodialysis.	14th March 2016
Tofacitinib	5 mg Tablets	Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs)	1st April 2016
Ceftaroline Fosamil	600 mg/Vial Injection	Adult (18 years of age patients with community-acquired pneumonia	9th May 2016
Panobinostat	Hard Gelatin Capsules 10mg/15mg/20mg (Panobinostat lactate)	In combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma, who have received at least 1 prior therapy	27th May 2016
Bepotastine Besilate	Bulk & Bepotastine Besilate 1.5 %w/v Ophthalmic solution	Itching associated with allergic conjunctivitis	8th June 2016
Ibutilide	Bulk & amp; Ibutilide Fumarate Injection 0.1mg/ml	For the rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm. Patient with atrial arrhythmias of longer duration are less likely to respond to Ibutilide Fumarate Injection. The effectiveness of Ibutilide has not been determined in patients with arrhythmias of more than 90 days in duration	10th June 2016

Reference: http://www.cdsco.nic.in/forms/list.aspx?lid=2034&Id=11. (Last accessed on June 30, 2016)

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DEPARTMENT OF PHARMACY PRACTICE NEWS

Patient Counselling Centre at KS Hegde Charitable Hospital

The Department of Pharmacy Practice, Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Nitte University has been established Patient Counselling Centre at KS Hegde Charitable Hospital, Deralakatte, Mangalore in the month of May 2016. The aim of this patient counselling centre is to educate the patients and their attendants to the safe use of medications.



Faculty members counselling the patients at the Patient Counselling Centre

PhD Award

Dr. Juno J. Joel, Asst. Professor, Dept. of Pharmacy Practice, Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences has been awarded Doctor of Philosophy (Ph.D.) for his thesis entitled "A Critical Study on Drug Utilization and Evaluation of Patients with Schizophrenia in a Tertiary Care Hospital of Dakshina Kannada District" by Nitte University, Mangalore.

International Travel Scholarship Award to Dr. Uday Venkat Mateti

Dr. Uday Venkat Mateti, Asst. Professor, Dept. of Pharmacy Practice, Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences has been awarded Multinational Association of Supportive Care in Cancer (MASCC) International Travel Scholarship - 2016 during the MASCC Annual Meeting on Supportive Care in Cancer, 22-25 June 2016, Adelaide, Australia. As a recipient of a Travel Scholarship, he has been awarded free conference registration completed by MASCC prior to the Meeting and also inclusive of airfare, hotel, meals and ground transportation up to an amount limit of $1200 USD.


The 2016 MASCC Meeting Travel Scholarship Award, was sponsored by the noble mission of the Multinational Association of Supportive Care in Cancer to promote the innovative research in the field of Supportive Care in Cancer; a very novel vision, and beneficial for the young scientists in India. MASCC encouraged young scholars such as Dr. Mateti UV, to participate in the esteemed MASCC Annual Meeting on Supportive Care in Cancer, held in Adelaide, Australia, 22-25 June 2016. During the Annual Meeting, he presented the research paper entitled "Predictors of Anxiety and Depression among Cancer Patients in a Tertiary Care Teaching Hospital"

Nitte Institutions

Health Science Institutions, Hospitals and Research Centres

1. K.S. Hegde Medical Academy, Mangaluru
2. A.B. Shetty Memorial Institute of Dental Sciences, Mangaluru
3. Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Mangaluru
4. Nitte Usha Institute of Nursing Sciences, Mangaluru
5. Nitte Institute of Physiotherapy, Mangaluru
6. Nitte Institute of Medical Laboratory Sciences, Mangaluru
7. Nitte Institute of Speech and Hearing, Mangaluru
8. Justice K. S. Hegde Charitable Hospital, Mangaluru
9. Nitte Meenakshi Institute of Craniofacial Surgery, Mangaluru
10. Leela Narayana Shetty Memorial Cancer Institute, Mangaluru
11. Nitte-Gajria Hospital, Karkala
12. Kshema-IVF: Fertillity & Reproductive Medicine Centre, Mangaluru
13. Nitte Rural Psychiatry Centre, Nitte.
14. Kowdoor Gopal Hegde & Smt. Manorama Hegde Hospital, Bailur.
15. Nitte University Centre for Science Education & Research (NUCSER), Mangaluru
16. Nitte University Centre for Animal Research & Experimentation (NUCARE), Mangaluru
17. Nitte University Centre for Stemcell Research & Regenerative Medicine (NUCSReM), Mangaluru

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18. Nitte Mahalinga Adyanthaya Memorial Institute of Technology, Nitte
19. Nitte Meenakshi Institute of Technology, Bengaluru
20. Nitte Institute of Architecture, Mangaluru

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21. Justice K. S. Hegde Institute of Management (Dept. of Management Studies, NMAMIT, Nitte), Nitte
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23. Sarosh Institute of Hotel Administration, Mangaluru
24. Nitte Institute of Banking & Finance, Mangaluru
25. Nitte Institute Communication, Mangaluru

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27. Mulki Ramakrishna Punja Industrial Training Institute, Thokur

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29. Dr. Nitte Shankara Adyanthaya Memorial First Grade College, Bengaluru
30. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Nitte
31. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Mangaluru
32. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Bengaluru

Schools

33. Dr. Nitte Shankara Adyanthaya Memorial Senior Secondary School, Nitte
34. Dr. Mundkur Ramanna Shetty Memorial English Medium High School, Thokur
35. Nitte International School, Bengaluru
36. Dr. Nitte Shankara Adyanthaya Memorial Higher Primary School, Bolakodi

Satellite Health Centres:

Bailur | Bellikoth | Bengre | Dabbekatte | Farangipet | Hejamadikodi | Kadri | Karkala | Mangalagangothri | Madikeri | Mukka | Mulki | Mundkur | Nada | Nitte | Sasihithlu | Sringeri | Subrahmanya | Thalipadi